

BEAR® 1000 VENTILATOR MAINTENANCE MANUAL

50000-12131



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WARNING

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ALL MAINTENANCE PERFORMED WITHIN THE APPLICABLE WARRANTY PERIOD (SEE WARRANTY CARD) MUST BE AUTHORIZED IN ADVANCE BY A BEAR MEDICAL SYSTEMS, INC. SERVICE REPRESENTATIVE IN ORDER TO RETAIN THE WARRANTY STATUS OF THE SUBJECT UNIT.

WARNINGS AND CAUTIONS

Statement in this manual preceded by the following words are of special significance.

WARNING

means there is the possibility of personal injury or death to yourself and others.

CAUTION

means there is the possibility of damage to the instrument or other property.

NOTE

indicates points of particular interest for more efficient and convenient operation.

It is recommended that the reader take particular notice of the warnings, cautions, and notes provided throughout this manual.

PREFACE

PROPRIETARY INFORMATION

INFORMATION CONTAINED WITHIN THIS MAINTENANCE MANUAL IS PROPRIETARY TO BEAR MEDICAL SYSTEMS, INC., AND MAY BE USED ONLY FOR THE PURPOSE OF PROVIDING MAINTENANCE. THE PURCHASE, RECEIPT OR POSSESSION OF THIS MAINTENANCE MANUAL DOES NOT CONFER, TRANSFER, OR LICENSE ANY OTHER RIGHTS IN THIS INFORMATION. ANY OTHER USE OR DISCLOSURE AND/OR REPRODUCTION (by any method) OF THE INFORMATION CONTAINED HEREIN IS PROHIBITED UNLESS EXPRESSLY PERMITTED HEREIN.

INTRODUCTION

The BEAR® 1000 Ventilator Maintenance Manual contains electrical and mechanical verification, calibration, troubleshooting and replacement instructions prepared to assist a qualified biomedical technician in the maintenance of the ventilator.

The Maintenance Manual is specifically intended for use by an authorized service person. Any adjustments or procedures that exceed the scope of this manual should be referred to a Bear Medical Systems Factory Service Center. For specific operating instructions and clinical theory of operation, refer to the BEAR® 1000 Ventilator Instruction Manual (50-10613-00). Maintenance personnel should become thoroughly familiar with the Operating and Repair techniques before servicing this equipment.

Page Numbering – The page numbering system used throughout this manual is as follows:

• June 1993

The month/year following the page number indicates the revision level of the individual page. When a page(s) has been revised, the month and year will be updated. Where no change has occurred, the month and year will remain unchanged even though the page may have been reprinted in the revision process.

50000-12029

This indicates the part number of the base manual or component section.

NOTE

Sections 3 and 9 have different part numbers, as they were prepared as individual documents. They do

interrelate to the base maintenance manual.

WARNING

When a GAS SUPPLY FAILURE alarm occurs, the Blender will use the remaining gas supply. This means that the oxygen concentration delivered to the patient may differ from the clinician-selected O2 setting.

WARNING

The Operator Diagnostics must never be performed when the ventilator is connected to a patient. To do so could result in serious injury to the patient.

WARNING

The following warnings must be read and understood before performing the procedures described in this section.

Under no circumstances should this medical device be operated in the presence of flammable anesthetics or other volatile materials due to a possible explosion hazard.

Liquid spilled or dripped into the unit may cause damage to the unit or result in an electrical shock hazard.

Oxygen vigorously accelerates combustion. To avoid violent ignition, do not use any gauges, valves, or other equipment that has been exposed to oil or grease contamination.

Do not release this medical device if any alarm/alert function is inoperative. To do so could result in a malfunction without warning, possibly resulting in personal injury up to including death or property damage. Refer the unit to a Bear Medical Systems Authorized Service Technician or a Bear Medical Systems Trained Hospital Service Technician.

WARNING

All tubing and fittings used to connect high pressure gas (air and oxygen) from the source to the test equipment and from the test equipment to the device being tested must be capable of withstanding a minimum supply pressure of 100 psi (7.03 kg/cm²). The use of tubing and fittings not capable of withstanding this pressure could cause the tubing to rupture, resulting in personal injury or property damage.

When verifying the operation of this medical device, do not breathe directly from the machine. Always use a fresh bacterial filter and test circuit. A hazard to the health of the service person may result.

If any of the following procedures cannot be verified as outlined in this document, do not use this device on a patient and refer it to Bear Medical Systems or a Bear Medical Systems Authorized Service Facility or a Bear Medical Systems Trained Hospital Service Technician.

WARNING

Do not release the ventilator for use if it does not pass all of the verification procedures specified in the checklist. To do so could result in personal injury including death or property damage. Refer the ventilator to a Bear Medical Service Technician or a Bear Medical Systems trained service technician for appropriate repair and/or calibration.

WARNING

When replacing air O₂ inlet filters, mark and remove one and only one fitting at a time. Replace the filter and return the fitting to its original location before removing the second fitting. Failure to follow this procedure may result in injury, including death, to the patient.

**BEAR MEDICAL SYSTEMS, INC
STANDARD WARRANTY**

Bear Medical Systems, Inc. standard warranty is extended to the original buyer purchasing the equipment directly from Bear Medical Systems, Inc. or through its authorized dealers. All warranty periods, where applicable, commence on the date of first purchase but not more than six months after shipment from Bear Medical Systems, Inc. Bear Medical Systems' sole obligation and liability under this warranty is limited to (at Bear Medical Systems option) the repair or replacement by Bear Medical Systems authorized personnel of any parts or assemblies which, upon test and examination by Bear Medical Systems prove to be defective. This equipment may be returned prepaid to Bear Medical Systems after prior notification has been given and approval obtained for the return.

This warranty does not cover normal maintenance such as cleaning, adjustment, or lubrication and updating of equipment or parts thereof. This warranty shall be void and not apply if the equipment, including any of its parts, is modified without Bear Medical Systems authorization; is attempted to be repaired by personnel not authorized by Bear Medical Systems; is not maintained in accordance with the prescribed schedule; is used with accessories or parts not authorized; or is damaged due to misuse, mishandling, abuse, negligence, accident, fire, or inadequate packaging by owner for shipment. Bear Medical Systems makes no guarantee of clinical results.

THE WARRANTY STATED ABOVE (INCLUDING ITS LIMITATIONS) IS THE ONLY WARRANTY MADE BY BEAR MEDICAL SYSTEMS AND IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. BEAR MEDICAL SYSTEMS SHALL NOT BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND.

Warranty period is one year with the following exceptions:

1. Preventive maintenance (90 day) warranty on all parts and labor included in all procedures.

Table of Contents

Specifications	1
Theory of Operations	2
Operational Verification Procedures	3
Updates.....	4
Calibration	5
Schematics	6
Troubleshooting	7
Removal and Replacement	8
Preventative Maintenance.....	9
Parts List	10
Repacking /Shipping Instructions.....	11

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Section 1

BEAR® 1000 Ventilator

Specifications

Modes.....	1
Breath Rate.....	1
Gas Delivery System.....	2
Inspiratory Pressure Control.....	4
PEEP.....	5
Oxygen Control.....	5
Nebulizer Gas Source.....	5
Monitors.....	5
Rate/Time Monitors.....	6
Pressure Monitors.....	6
Inspiration Source/Type.....	7
Hour Meter.....	7
Alarms/Safety Requirements.....	8
Volume Alarms.....	8
Rate/Time Alarms.....	8
Pressure Alarms.....	9
Failed to Cycle.....	10
Power Fail.....	10
Cross Contamination of Supply Gases.....	10
Maximum Sound Levels.....	10
Analog Outputs.....	10
RS-232 Port.....	10
Gas Fail.....	11
Patient Circuits.....	11
Endotracheal Tubes.....	11
Nebulizers.....	11
Humidification.....	11
Pneumatic Supply Requirements.....	11
Electrical Supply.....	12
Environmental Requirements.....	12
Error History.....	12
Cleaning.....	12
Sterilization.....	13

MODES

Assist CMV (Assist Controlled Mechanical Ventilation).

A volume breath shall be delivered to the patient when a breath interval (as determined by the preset breath rate) elapses or the patient activates the assist trigger. The breath interval shall be reset at the start of every volume breath, thus the patient may trigger every breath if he/she is breathing faster than the preset breath rate. On the other hand, if the patient is not active, he/she shall get breaths at the regular interval of the preset breath rate.

Demand breathing is not allowed in this mode, however, volume breaths may be flow and volume augmented.

SIMV/CPAP (Synchronous Intermittent Mandatory Ventilation/ Continuous Positive Airway Pressure)

SIMV - Preset breath rate is greater than 0

When the breath interval elapses (as determined by the preset breath rate), a mandatory breath window will be opened. A volume breath will be delivered when the patient activates the assist trigger while the window is open. As soon as the volume breath is triggered, the window will be closed and the patient may breathe spontaneous (or pressure supported) breaths until the next breath interval elapses when the cycle starts over.

Note that the breath interval is reset as soon as it elapses, even though a volume breath has not necessarily been delivered.

If a breath interval elapses and the mandatory breath window is still open, then a volume breath will be delivered. The window will remain open until the patient triggers the assist trigger.

CPAP - Preset breath rate equals 0

If the preset breath rate is set to zero, then demand breathing shall be enabled and the patient shall breathe spontaneous or (pres-

sure supported) breaths exclusively except for manual volume breaths.

Press Control (Pressure Control Ventilation) (N/A FOR BASIC UNIT)

A pressure controlled breath shall be delivered to the patient when a breath interval (as determined by the preset breath rate) elapses or the patient activates the assist trigger. The breath interval shall be reset at the start of every pressure controlled breath, thus, the patient may trigger every breath if he/she is breathing faster than the preset breath rate. On the other hand, if the patient is not active, he/she shall get breaths at the regular interval of the preset breath rate.

BREATH RATE

Normal Breath Rate

Range: 0, 0.5, 1 - 120 bpm

Resolution: 0.5 bpm from 0 to 1 bpm
1 bpm for remainder

Tolerance: 0-60 bpm - ± 1 bpm
61-100 bpm - $\pm 2\%$ of setting
101-120 bpm - $\pm 3\%$ of setting

Sigh Breath Rate (N/A FOR BASIC UNIT)

Range: Every 100 breaths

Sigh Interval Assist CMV: 2 x Normal Breath Interval

SIMV/CPAP: Normal Breath Interval

Limitation: Not active in pressure control mode.

Assist Sensitivity (Assist Trigger)

Range: 0.2 to 5.0 cmH₂O

Resolution: 0.1 cmH₂O

SPECIFICATIONS

Manual Breath

The manual breath control delivers a single volume breath (in Assist CMV or SIMV/CPAP) or a pressure controlled breath (in Press Control mode) if the ventilator is not in the inspiratory cycle of a breath.

Assist CMV The breath interval will be reset just as if the patient had initiated the breath.

SIMV/CPAP The breath interval will be reset and the mandatory breath window will be opened upon completion of the volume breath. If breath rate is set to 0 (i.e., CPAP), the breath window will not be opened.

Press Control

The breath interval will be reset just as if the patient had initiated the breath.

Minimum Minute Volume (MMV) (N/A FOR BASIC UNIT)

MMV will guarantee that the ventilator delivers a minimum minute volume (MMV). If the monitored exhaled minute volume drops below the set MMV level and the set value for MMV is greater than the product of the breath rate and tidal volume control settings, then the breath rate will automatically be increased to MMV divided by tidal volume (MMV breath rate). The breath rate will return to the normal breath rate once the monitored exhaled minute volume exceeds the MMV level by 1 LPM or 10%, whichever is greater.

Range: 0 to 50L.

Resolution: 1.0 L.

Limitation: Only active in SIMV/CPAP Mode

End Expiratory Hold (N/A FOR BASIC UNIT)

Shall not allow the patient to inspire, or exhale any gas. End expiratory hold shall be initiated upon the detection of the next breath.

Limitation: The maximum duration of an end expiratory pause shall be 9.0 ± 0.1 seconds.

GAS DELIVERY SYSTEM

Limitations The maximum minute volume that the ventilator shall be able to deliver is at least 50 L.

If an attempt is made to exceed Maximum Minute Volume, the instantaneous flow capability of the machine will be limited. This will cause peak flow to be limited, which will extend inspiration time. It will in turn be limited by the Max time for inspiration or Max I:E Ratio.

Volume Breath Control

The purpose of a volume breath is to deliver a pre-determined volume of gas to the patient. The preset tidal volume, peak flow and waveform determine how the flow is delivered.

Norm Range 0.10 to 2.00 L.

Sigh Range: $1.5 \times \text{Normal}$ (N/A FOR BASIC UNIT)

Tolerance: $\pm 10\%$ of setting or $\pm 0.02\text{L.}$, whichever is greater.

Resolution: 0.01L.

Limitation: Volume accuracy assumes a standard temperature of 25° C (77°F) and set barometric pressure.

Peak Flow

Range: 10 to 150 lpm

Tolerance: ± 10% of setting or ±3 lpm, whichever is greater

Resolution: 1 lpm

Waveform

During the delivery of a volume breath, flow shall be delivered in one of the three user selectable waveforms.

Square Wave

Deliver gas at the set peak flow for the duration of the inspiration. However, since flow cannot be changed from zero to the peak flow instantaneously, an ideal square wave will not be delivered.

Sine Wave (N/A FOR BASIC UNIT)

Deliver gas beginning at zero and increasing to the peak flow setting and then decreasing back to zero in a fashion that depicts a sinusoid.

Decelerating Wave (N/A FOR BASIC UNIT)

Deliver gas beginning at the peak flow and continuously decreasing linearly until the flow reaches 50% of the peak flow. However, since flow cannot be changed instantaneously an ideal decelerating wave cannot be delivered.

Inspiratory Pause

Once the preset tidal volume of a volume breath has been delivered, the patient will not be allowed to exhale for a specified amount of inspiratory pause time.

Preset Pause (N/A FOR BASIC UNIT)

A preset inspiratory pause will be delivered with each volume breath.

Range: 0.0 to 2.0 sec

Resolution: 0.1 sec

Manual Pause

A single inspiratory pause shall be delivered, once per actuation of the manual pause control.

Limitation: The maximum duration of an inspiratory pause shall be 2.0 ± 0.1 seconds.

Compliance Compensation (N/A FOR BASIC UNIT)

The volume of gas delivered during a volume breath shall be increased so that it includes the volume intended for the patient plus the volume lost due to the compliance effect of the circuit. During the delivery of all volume breaths, the ventilator will determine the pressure at the end of the inspiration. The volume delivered during the next volume breath will be increased by the difference between the end inspiratory pressure and PEEP times the compliance compensation factor.

Range: 0.0 to 7.5 ml/cmH₂O

Resolution: 0.1 ml/cmH₂O

Limitation: Not active for sigh volume breaths.

Maximum Flow Acceleration

The maximum rate at which flow can be changed.

Range: 64,000 lpm² (0.1 to 0.25 l)
108,000 lpm² (0.25 to 3.00 l)

Limit: If an attempt is made to exceed Max flow acceleration, then peak flow will not be achieved for a square or decelerating waveform. Tidal volume will be delivered low for a sine wave.

SPECIFICATIONS

Maximum Total Inspiratory Time

The maximum inspiratory time is 5.0 ± 0.1 seconds plus inspiratory pause time.

Limit: If an attempt is made to exceed Maximum Total Inspiratory Time, the breath will be immediately terminated causing tidal volume to be limited.

Maximum I:E Ratio (Max I:E)

The maximum inspiratory to expiratory ratio is 4:1 for the Comprehensive Unit and 1:1 for the Basic Unit

Limit: If an attempt is made to exceed Max I:E Ratio, the breath will be immediately terminated causing tidal volume to be limited.

Inspiratory Pressure Control

The ventilator has the capability to control the inspiratory pressure in the circuit. This includes spontaneous, pressure supported and pressure controlled breaths, as well as flow, volume and pressure augmentation. Except for flow and volume augmentation, the pressure achieved shall be the inspiratory pressure level plus preset PEEP. For flow and volume augmentation, the pressure achieved shall be preset PEEP.

Inspiratory Pressure Level

Range: 0 to 80 cmH₂O

Tolerance: ± 3 cmH₂O

Stability: ± 3 cmH₂O

Min Guaranteed Flow 150 lpm

Inspiratory Pressure Slope (N/A FOR BASIC UNIT)

The user shall have the capability to control the slope at which the inspiratory pressure level is achieved. This control shall be a relative control of slow to fast.

Range: (Pediatric) -P9 to P9
(Adult) -9 to 9

Resolution: 1

Demand Breaths

In those modes where demand breathing is allowed, a demand breath will be triggered by the assist trigger. The patient demand will be met by providing enough flow to achieve the inspiratory pressure level plus PEEP. The pressure will be maintained at this level until the patient stops demanding, at which time the pressure will be returned to the preset PEEP level.

A Spontaneous Breath is a demand breath where the inspiratory pressure level equals zero.

A Pressure Supported Breath is a demand breath where the inspiratory pressure level is greater than zero.

Pressure Controlled Breaths (N/A FOR BASIC UNIT)

During the delivery of a pressure controlled breath, pressure in the circuit will be increased to the inspiratory pressure level and maintained for the duration of the breath. The breath shall be terminated when the preset inspiratory time elapses and will not relieve pressure if the patient fights the breath.

Insp Time: 0.1 to 5 sec

Resolution: 0.1 sec

Flow & Volume Augmentation

When a patient demands more gas than is being delivered by a volume breath, due to the preset settings, tidal volume and peak flow, additional gas will be delivered in order to maintain the circuit pressure at PEEP. The additional gas will be delivered as long as the patient is demanding, even if the delivered volume exceeds the preset tidal volume. Note, both flow and volume augmentation will be affected by "inspiratory pressure slope".

Pressure Augmentation (N/A FOR BASIC UNIT)

Without pressure augmentation, the ventilator shall deliver a volume breath based on the preset tidal volume, peak flow, waveform and patient demand (i.e., flow & volume augmentation). With pressure augmentation, the minimum pressure level maintained by the ventilator during a volume breath will be raised from PEEP to PEEP plus the inspiratory pressure level. The minimum pressure level will be maintained until the preset tidal volume has been delivered and the patient stops demanding.

PEEP (Positive End Expiratory Pressure)

The pressure that shall be maintained in the patient circuit at the end of exhalation.

Range: 0 to 50 cmH₂O

Resolution: 1 cmH₂O

Stability: Pressure may not fluctuate by more than ± 1 cmH₂O within one breath cycle (i.e., including undershoot).

Leaks: Maintain PEEP for leaks up to 25 lpm.

Oxygen Control

Percent Oxygen

The machine shall control the percentage of oxygen in the delivered gas. Normal air is 21% oxygen (O₂) and 78% nitrogen (N₂).

Range: 21 to 100 percent

Tolerance: $\pm 4\%$ O₂ (Full Scale)

Resolution: 1% O₂

Stability: $\pm 1\%$ O₂ within one inspiratory cycle.

100% Oxygen (N/A FOR BASIC UNIT)

Deliver 100% oxygen for 3.0 ± 0.1 minutes regardless percent oxygen setting.

Nebulizer Gas Source

The machine shall provide blended gas, per set O₂ percentage, at approximately 10.0 ± 1.5 psig when a nebulizer is attached and the nebulizer gas source is activated. The gas shall only be delivered during the inspiratory cycle of a breath so that the delivery of nebulized gas will be synchronized with the patient's breathing.

Activation: Once the calculated delivered flow is determined to be greater than or equal to 20 +5, -15 lpm (Active for all breaths).

Limitations: Volume accuracy shall be $\pm (10 + 200/\text{peak flow})\%$ or $\pm (2/\text{tidal volume} + 200/\text{peak flow})\%$ for nebulizers that generate between 4 to 8 lpm with a 10 psig gas source.

The maximum duration the nebulizer gas source shall be activated is 30.0 ± 0.1 minutes.

MONITORS

Volume Monitors

Exhaled Tidal Volume

Range: 0 to 9.99 L.

Tolerance: $\pm 10\%$ of the exhaled volume or $\pm .03$ L., whichever is greater.

Resolution: .01 L.

Exhaled Minute Volume

Range: 0.0 to 99.9L.

Tolerance: $\pm 10\%$ of the exhaled volume or ± 0.3 L., whichever is greater

Resolution: 0.1L.

SPECIFICATIONS

Response: The monitored exhaled minute volume will decay to the actual average exhaled minute volume within 30 seconds from the time the actual exhaled minute volume changes.

Spontaneous Minute Volume (N/A FOR BASIC UNIT)

Range: 0.0 to 99.9 L.

Tolerance: $\pm 10\%$ of the exhaled volume or ± 0.3 L., whichever is greater

Resolution: 0.1L.

Response: The monitored spontaneous exhaled minute volume will decay to the actual average exhaled minute volume within 30 seconds from the time the actual spontaneous exhaled minute volume changes.

Percent MMV (% MMV) (N/A FOR BASIC UNIT)

Monitor the percentage of time, over the last 30 minutes, that the ventilator has been using the MMV breath rate instead of the normal breath rate.

Range: 0 to 100%

Tolerance: $\pm 1\%$

Resolution: 1%

Rate/Time Monitors

Breath Rate

Monitor the number of breaths per minute (bpm) that the patient is inspiring. This includes all breath types.

Range: 0 to 155 bpm

Tolerance: $\pm 3\%$ of reading or ± 2 bpm, whichever is greater

Resolution: 1 bpm

Response: The monitored breath rate will

decay to the actual average breath rate within 30 seconds from the time the actual breath rate changes.

Spontaneous Breath Rate (N/A FOR BASIC UNIT)

Monitor the number of breaths per minute (bpm) that the patient is inspiring due exclusively to demand breathing (spontaneous or pressure supported breaths).

Range: 0 to 155 bpm

Tolerance: $\pm 3\%$ of reading or ± 2 bpm, whichever is greater

Resolution: 1 bpm

Response: The monitored spontaneous breath rate will decay to the actual average spontaneous breath rate within 30 seconds from the time the actual spontaneous breath rate changes.

I:E Ratio (N/A FOR BASIC UNIT)

For all volume and pressure controlled breaths (i.e., not active for demand breathing), measure the inspiratory and expiratory time and calculate the I:E ratio as follows:

Range: 1:0.1 to 1:99.9

Resolution: 0.1

Pressure Monitors

Peak Pressure (N/A FOR BASIC UNIT)

Monitor the maximum pressure in the patient circuit measured during the inspiratory phase of a breath.

Range: 0 to 140 cmH₂O

Tolerance: $\pm 3.5\%$ of reading or ± 2 cmH₂O, whichever is greater

Resolution: 1 cmH₂O

Limitation: Not active for spontaneous breaths

Mean Airway Pressure (N/A FOR BASIC UNIT)

Monitor the average pressure in the patient circuit for the last 30 second interval.

Range: 0 to 140 cmH₂O

Tolerance: $\pm 3.5\%$ of reading or ± 2 cmH₂O, whichever is greater

Resolution: 1 cmH₂O

Response: The monitored mean airway pressure will decay to the actual mean airway pressure within 30 seconds from the time the actual mean airway pressure changes.

Plateau Pressure (N/A FOR BASIC UNIT)

Monitor the circuit pressure during the time that a volume breath is in an inspiratory pause.

Range: 0 to 140 cmH₂O

Tolerance: $\pm 3.5\%$ of reading or ± 2 cmH₂O, whichever is greater

Resolution: 1 cmH₂O

Limitation: If no plateau occurs, then the displayed plateau pressure shall equal 0.

Proximal Pressure

Continuously monitor the pressure in the patient circuit.

Range: -10 to 120 cmH₂O

Tolerance: ± 3 cmH₂O or 3%, whichever is greater.

Resolution: 1 cmH₂O

Air Inlet Pressure

Continuously monitor the pressure of the inlet air gas supply.

Range: 0 to 100 psig, or 0 to 160 psig

Tolerance: ± 5 psig

Resolution: 5 psig or better

Oxygen Inlet Pressure

Continuously monitor the pressure of the inlet oxygen gas supply.

Range: 0 to 100 psig, or 0 to 160 psi

Tolerance: ± 5 psig

Resolution: 5 psig or better

Inspiration Source/Type

Indicate the type and source of the breath being delivered as well as whether MMV is active, based on the following classification:

Controlled A normal volume or pressure controlled breath

Sigh A sigh volume breath (N/A FOR BASIC UNIT)

Patient Effort A breath is assist triggered, flow or volume augmented, or is a demand breath (spontaneous or pressure supported)

MMV Active Ventilator is using MMV breath rate (N/A FOR BASIC UNIT)

Hour Meter

A non-resettable meter used to measure and display the total amount of time that the ventilator has been on. This shall be independent of whether or not gas is being delivered.

Range: 0 to 99,999 hours

Tolerance: $\pm 2\%$ of reading

Resolution: 0.1 hour

Alarms/Safety Requirements

Alarm Features

Whenever a monitored value violates its alarm limit, an alarm shall be activated. The following conditions apply to all alarms:

Audible Indicator

An audible indicator shall occur whenever an alarm is activated and it shall continue to occur until the alarm is no longer violated. The audible indicator shall occur for a minimum of 2 seconds once activated.

Limitation: High peak pressure limit shall have a minimum of 1 second.

Alarm Silence

Disables the audible indicator and displays a visual indicator for 60 seconds. It works for all alarms except when the "Failed to Cycle" alarm is active.

Tolerance: ± 1 second

Visual Indicator

Each alarm shall have a red visual indicator that shall occur whenever the alarm is activated. The visual indicator shall continue to occur until the alarm limit is no longer violated and the alarm reset has been activated.

Alarm Reset

Deactivates the visual indicator for all alarms that are no longer violated.

Lamp Test

Activates all audible and visual indicators for approximately 4 seconds.

Volume Alarms

Low Exhaled Minute Volume

Range: 0.0 to 50.0 L.

Tolerance: ± 0.1 L. of the monitored exhaled minute volume

Resolution: 0.1 liter

High Exhaled Minute Volume

Range: 0.0 to 80.0 L.

Tolerance: ± 0.1 L. of the monitored exhaled minute volume

Resolution: 0.1L.

Rate/Time Alarms

Low Breath Rate

Range : 3 to 99 bpm

Tolerance: ± 1 bpm of the monitored breath rate

Resolution: 1 bpm

High Breath Rate

Range: 0 to 155 bpm

Tolerance: ± 1 bpm of the monitored breath rate.

Resolution: 1 bpm

Inspiratory Time /I:E Limit

A. Maximum Inspiratory Time

If the inspiratory time of a volume breath exceeds 5 seconds plus inspiratory pause time, or the inspiratory time of a pressure controlled or demand breath exceeds 5 seconds, the ventilator shall alarm and terminate the breath.

Range : 5.0 seconds + inspiratory pause time

Tolerance: + 0.1 seconds

B. Maximum I:E Ratio

If the inspiratory time for a volume or pressure controlled breath exceeds the maximum I:E Ratio interval, the ventilator shall alarm and terminate the breath.

a) I:E Override NOT active.

I:E Ratio Interval: $(1/f) * .5$ (1:1)

f = Cycles/Second

b) I:E Override active (N/A FOR BASIC UNIT)

I:E Ratio Interval: $(1/f) * .80$ (4:1)

f = Cycles/Second

Limitation: Not active for demand breaths (spontaneous and pressure supported).

Pressure Alarms

Low Inspiratory Pressure

Alarm if the peak pressure during an inspiration is less than the low inspiratory pressure limit.

Range : 3 to 99 cmH₂O

Tolerance: ± 1 cmH₂O of monitored peak pressure.

Resolution: 1 cmH₂O

Limitation: Not active for spontaneous breaths and pressure supported/pressure control breaths when PEEP + Insp. Press ≤ 3 cmH₂O.

High Peak Pressure Limit

If the high peak pressure limit is violated, the inspiration shall be terminated and circuit pressure shall return to PEEP + 5 ± 1.5 cmH₂O before the next breath may be delivered.

A. Normal High Peak Pressure Alarm

Alarm if the pressure in the patient circuit exceeds the normal high peak pressure alarm except during sigh breath cycles.

Range : 0 to 120 cmH₂O

Tolerance : ± 1 cmH₂O of monitored peak pressure

Resolution: 1 cmH₂O

Limitation: Not active for Sigh Breaths

B. Sigh High Peak Pressure Alarm

Alarm if the pressure in the patient circuit exceeds the sigh high peak pressure alarm during a sigh breath cycle.

Range: $1.5 * (\text{Normal High Peak Pressure})$ to a maximum of 120 cmH₂O.

Tolerance: ± 1 cmH₂O of the monitored peak pressure.

Limitation : Only active for Sigh Breaths.

Low Baseline Pressure (N/A FOR BASIC UNIT)

Alarm if the baseline pressure (PEEP) is less than the Low Baseline Pressure Limit.

Range : 0 to 50 cmH₂O

Tolerance: ± 1 cmH₂O or 5% of the monitored PEEP, whichever is greater.

Resolution: 1 cmH₂O

Limitation: The alarm is off if it is set to zero.

High Baseline Pressure (N/A FOR BASIC UNIT)

Alarm if the baseline pressure (PEEP) is greater than the High Baseline Pressure Limit.

Range : 0 to 55 cmH₂O

Tolerance: ± 1 cmH₂O or 5% of the monitored PEEP, whichever is greater.

SPECIFICATIONS

Resolution: 1 cmH₂O

Proximal Disconnect

If the proximal pressure is below 3 cmH₂O and the Machine Pressure is greater than or equal to the High peak Pressure Alarm plus 10 cmH₂O, the alarm shall be activated and the inspiration shall be terminated. Patient triggered breaths shall not be detected but Breath Rate control and Demand Flow shall remain active.

Tolerance: ± 1 cmH₂O of monitored pressure

Resolution: 1 cmH₂O

Maximum Circuit Pressure Limit

An independent mechanism shall exist which shall relieve pressure at the patient wye at a maximum of 175 cmH₂O.

Failed to Cycle

If the ventilator fails to cycle for any reason, it shall alarm and allow the patient to breathe room air. PEEP shall not be maintained.

Power Fail

If power is removed from the unit, an audible indicator shall occur for a minimum of 5 minutes. A "Failed to Cycle" condition shall also occur. The audible indicator shall continue to occur when power is restored until the alarm silence is activated.

Run Diagnostics

When the ventilator detects a fault that will allow a certain degree of ventilation to be maintained, the ventilator shall continue to ventilate the patient and the "Run Diagnostics" alarm will be activated to notify the clinician so that he may rectify the condition. This will occur only if it is more effective to continue ventilation than to assert the "Failed to Cycle" condition.

Cross Contamination of Supply Gases

The ventilator shall not allow the external

source of the supply gases to be cross contaminated.

Maximum Pressure Differential: 80 psig

Maximum Sound Levels

All sound levels shall be tested per ANSI S12.10-1985.

Normal Operating: 50 dbA max.

Alarms - Adjustable: 55 dbA min.
75 dbA max.

Analog Outputs

The ventilator shall contain 3 analog output signals:

A) Proximal Pressure

Range: -60 to 140 cmH₂O

Scale: 1 cmH₂O/25 mV

Tolerance: $\pm 5\%$ of reading or ± 50 mV, whichever is greater.

Zero Offset: 1.5 Vdc at 0 cmH₂O

B) Inspiratory/Expiratory Flow

Range: -300 to 200 lpm

Scale: 1 lpm/10 mV

Tolerance: $\pm 10\%$ of reading or ± 30 mV, whichever is greater.

Zero Offset: 3 Vdc at 0 lpm

C) Inspiratory/Expiratory Volume

Range: 0.00 to 3.00 l

Scale: 0.01 l/25 mV

Tolerance: $\pm 10\%$ of reading or ± 75 mV, whichever is greater.

Zero Offset: 0 Vdc at 0 L.

RS-232 Port

The ventilator shall contain an RS-232 port

for bi-directional communication of data. All control settings, alarm settings and monitor values will be available upon demand. At 19.2 K baud, the system shall continuously output the flow and pressure signal in real time.

Baud Rate: 1200, 2400, 9600 and 19200

Gas Fail

A) Loss of Single Gas Source

Alarm if either gas supply, air or oxygen fails, and ventilate the patient on the remaining gas supply. An alarm shall not occur if the oxygen gas supply fails and the percent oxygen is set to 21%.

B) Loss of Both Gas Sources

Alarm if both gas sources, air and oxygen, fail. A "Failed to cycle" condition shall also occur.

Patient Circuits

The machine shall work with all four foot to six foot adult and pediatric circuits that have resistances and compliances within the range defined below:

Adult:

Compliance: 1.12 - 3.0 ml/cmH₂O
Resistance: 0.04 - 0.12
cmH₂O/LPS/FOOT @
50 lpm

Pediatric:

Compliance: 0.215 - 0.322 ml/cmH₂O
Resistance: 0.90 - 1.0
cmH₂O/LPS/FOOT @
50 LPM

Endotracheal Tubes (ET Tubes)

This machine shall work with Et tubes of the following size that have corresponding resistances:

Size: 2.5 mm to 9 mm

Resistance: Rp50 to Rp5 (per ASTM F1100)

Nebulizers

The machine will only be guaranteed to work with nebulizers that utilize the machine's nebulizer gas source. Nebulizers attached to the gas source must perform within the limits specified under Nebulizer gas source.

Humidification

The ventilator shall work with the following humidification sources although they may not be used concurrently:

A. Heat and Moisture exchanges (Artificial Nose)

Resistance: 1.5 to 8.0 cmH₂O/LPS at
60 lpm
(Dry to fully saturated)

NOTE

Exhaled volume display will be affected if the exhaled gasses are not fully saturated.

Compliance : N/A

B. Humidifier Chamber

Maximum Resistance: 3.5 cmH₂O/LPS
at 30 LPM

Compliance: 0.2 to 1.5 ml/cmH₂O

Pneumatic Supply Requirements

Supply Air

Pressure Range: 30 to 80 psig

Temperature: 10 to 62°C

Humidity: Dew point of gas should be at least 3° F below the ambient temperature.

Minimum Flow: 80 lpm at 30 psig

Inlet Fitting: CGA-Diss body type,
No. 1160

SPECIFICATIONS

Supply Oxygen

Pressure Range: 30 to 80 psig

Temperature: 10 to 40°C

Humidity: Dew point of gas should be at least 3° F below the ambient temperature.

Minimum Flow: 80 lpm at 30 psig

Inlet Fitting: CGA-Diss body type, No. 1240

Electrical Supply

At nominal, a voltage drop with a duration of 400 msec below minimum value will not affect normal operation.

AC Line Power

120 VAC
Range: 95 to 135 VAC - 60Hz

100 VAC
Range: 80 to 110 VAC - 50/60Hz

220 VAC
Range: 176 to 242 VAC - 50/60 Hz

240 VAC
Range: 192 to 264 VAC - 50Hz

Maximum Input Power (Nominal)

Ventilator only: 150 watts maximum

Humidifier Outlet: 500 watts maximum

Graphics Display: 100 watts maximum

Environmental Requirements

Temperature

a) Ambient Storage:
-35 to 70° C (-31 to 158° F)

b) Ambient Operating
10 to 40° C (50 to 104° F)

Altitude/Barometric Pressure

Sea Level to 9,000 ft.
(14.7 psia) to (10.5 psia)
(760 mmHg) to (545 mmHg)

Humidity

a) Storage:
0 to 99% Rh (non-condensing)

b) Operating
0 to 95% Rh (non-condensing)

History of Detected Errors

Except for "gas fail", the ventilator shall record an error code for all Fail to Cycle and Run Diagnostics alarms. The last 16 error codes shall be retained when power is removed so that the ventilator will maintain a history of its failures.

Cleaning of External Surfaces

All external surfaces of the ventilator shall be able to be wiped clean with the following compounds:

A) Isopropyl Alcohol

*B) Chlorine Compounds

Maximum Concentration: 1:10

*C) Quaternary Ammonium Compounds

Maximum Concentration: 1:500

*** Note: These compounds are diluted by volume in water**

Sterilization

All parts of the ventilator that can come in contact with the patient expiratory gas and all parts of the breathing circuit external to the ventilator shall be sterilizable or disposable.

Methods of Sterilization

Ethylene oxide, maximum temperature 130° F (54° C)

Steam sterilization, maximum temperature 250° F (121° C)

Liquid Sterilization

- a) Cidex
- b) Sonacide

Minimum sterilization cycles before part replacement

a. Patient Circuit

Ethylene Oxide	240 cycles
Steam Sterilization	240 cycles
Liquid Sterilization	240 cycles

b. All other sterilizable components

Ethylene Oxide	240 cycles
Steam Sterilization	240 cycles
Liquid Sterilization	240 cycles

SPECIFICATIONS

APPENDIX I - FEATURE MATRIX

MODELS

BASIC

COMPREHENSIVE

MODE

Assist Control	YES	YES
SIMV/CPAP	YES	YES
Press Control	N/A	YES

CONTROL

Tidal Volume	0.10 - 2.00 l	0.10 - 2.00 l
Sigh Volume	N/A	1.5 * Vt
Compliance Comp (ml/cmH2O)	N/A	0 - 7.5
Breath Rate (bpm)	0, 0.5, 1 - 120	0, 0.5 1 - 120
Sigh Breath Rate	N/A	100th Breath
Peak Flow (lpm)	10 - 150	10 - 150
Wave Form	Sqr	Sqr, Dcl, Sine
Inspiratory Time (sec)	N/A	0.1 - 5
Inspiratory Pause (sec)	N/A	0 - 2
PEEP (cmH2O)	0 - 50	0 - 50
Assist Sensitivity (cmH2O)	0.2 - 5.0	0.2 - 5.0
Inspiratory Pressure (cmH2O)	0 - 80	0 - 80
Pressure Slope		
Pediatric	N/A	-P9 to P9
Adult	N/A	-9 to 9
Min. Minute Volume (lpm)	N/A	0 - 50
Percent Oxygen	21-100	21-100
100% O2	N/A	YES
Nebulizer	YES	YES
Man Breath	YES	YES
Leak MakeUp	YES	YES
Flow/Volume Augmentation	YES	YES
Pressure Augmentation	N/A	YES
End Expiratory Hold	N/A	YES
Manual Pause	YES	YES

MONITORS

Tidal Volume (Liters)	0 - 9.99	0 - 9.99
Minute Volume (lpm)	0 - 99.9	0 - 99.9
Spontaneous MV (lpm)	N/A	0 - 99.9
I:E Ratio	N/A	1:0.1 - 1:99.9
Breath Rate (bpm)	0 - 155	0 - 155
Spontaneous Breath Rate (bpm)	N/A	0 - 155
Peak Pressure (cmH2O)	N/A	0 - 140
Mean Pressure (cmH2O)	N/A	0 - 140
Plateau Pressure (cmH2O)	N/A	0 - 140
Proximal Pressure Gauge (cmH2O)	-10 - 120	-10 - 120
Percent MMV (% time/0.5hr)	N/A	0 - 100
Inspiration Source/Type	YES	YES
MMV Active	N/A	YES

ALARMS/INDICATORS

Alarm Silence	YES	YES
Low MV (lpm).	0 - 50.	0 - 50
High MV (lpm)	0 - 80.	0 - 80
Low Rate(bpm)	3 - 99.	3 - 99
High Rate (bpm)	0 - 155.	0 - 155
Low Insp Pressure (cmH20)	3 - 99.	3 - 99
High Insp Pressure (cmH20).	0 - 120.	0 - 120
Low Baseline Pressure (cmH20).	N/A.	0 - 50
High Baseline Pressure (cmH20)	N/A.	0 - 55
Time/I:E Limit	YES	YES
Gas Failed	YES	YES
Power Failed (Audible Only)	YES	YES
Failed To Cycle	YES	YES
Run Diagnostics.	YES	YES
I:E Override	N/A.	1:4

ELEC. INTERFACES

RS-232	YES	YES
Analog Outputs (Flow,Pres,Vol)	YES	YES
Humidifier AC Output.	YES	YES
Graphic Display AC Output.	YES	YES

Section 2

BEAR® 1000 Ventilator

Theory of Operation

Overview.....	1
Ventilator Pneumatics.....	1
Gas Inlet	1
Blender	2
Accumulator.....	2
Flow Control Valve	2
Pneumatic Diagram	3
SOPR Valve.....	4
Low Pressure Control System.....	4
Exhalation Valve.....	5
Nebulizer System	6
Ventilator Electronics	6
Electronics.....	6
Flow Delivery Logic	9
Volume Logic.....	9
Pressure Logic.....	9

THEORY OF OPERATION

OVERVIEW

This section provides an in-depth discussion of the operating theory of the BEAR® 1000 Ventilator. Included are descriptions of the:

- ventilator pneumatics,
- electronics (including Monitor PCB, Control PCB and EPI),
- flow delivery logic, and
- RS-232 protocol.

Figure 2-1 shows how these parts of the ventilator interrelate.

VENTILATOR PNEUMATICS

Figure 2-2 depicts the complete pneumatics of the BEAR® 1000 Ventilator.

GAS INLET SYSTEM

Compressed air and oxygen sources, supplied in the pressure range of 30 to 80 psig, are connected to the standard DISS male-threaded fittings on the rear of the ventilator.

Incoming gases pass through coalescing filters housed in the Air and O₂ Inlet Water Traps. The filters have a minimum retention efficiency of 95% for 0.7 micron particles and 2 micron droplets.

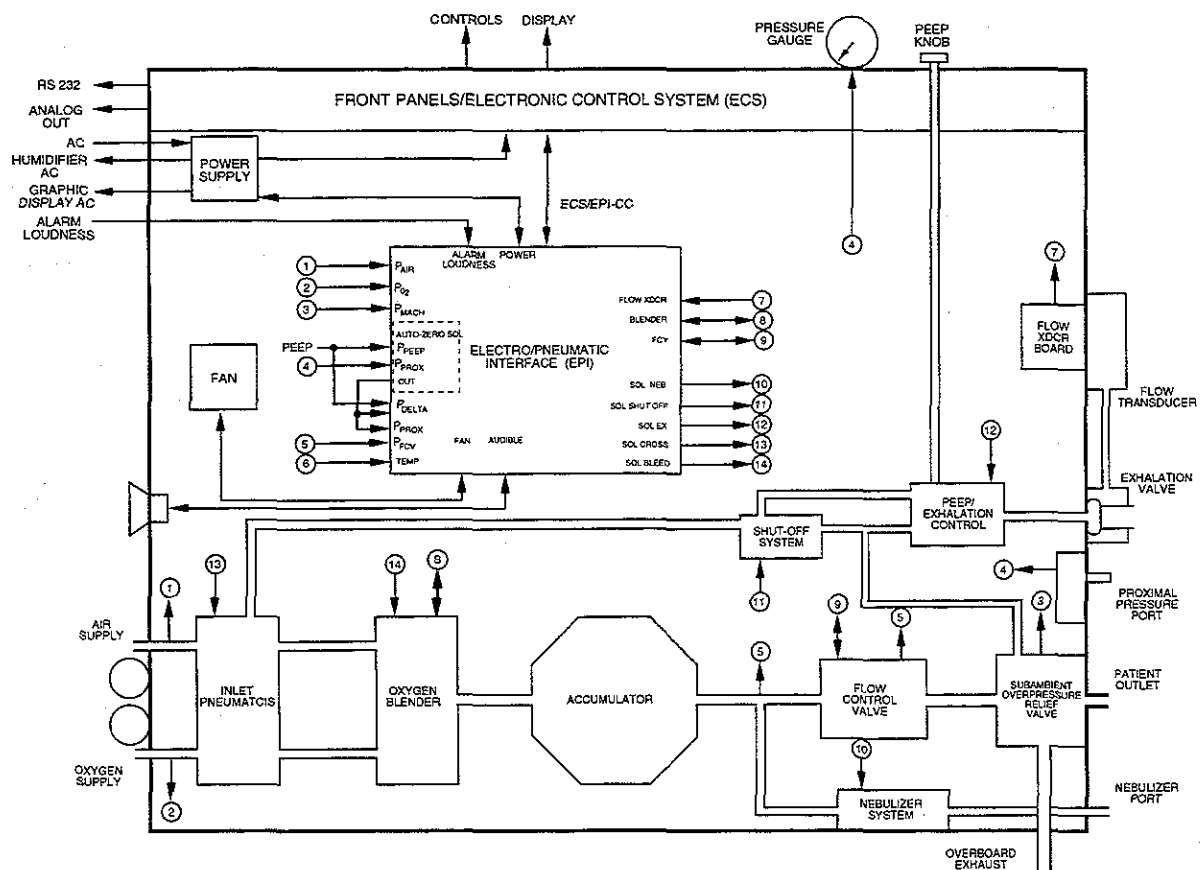


Figure 2-1

The inlet pressures of the gases are monitored by independent air and oxygen Inlet Pressure Transducers, and are displayed on their respective inlet pressure gauges. A drop in either gas pressure below 27.5 psig activates an audible and visual GAS SUPPLY FAILURE alarm.

From the Inlet Water Traps and Filters, the air and oxygen enter the in-line, one-way Check Valves which prevent gas backflow into the air and oxygen supply systems. To prevent check valve malfunction, compressed gases must be clean and dry.

The Air Regulator and Oxygen Relay create a balance of air and oxygen supply pressures. The Air Regulator reduces the air supply pressure to 18.0 psig and pilots the O₂ Relay to track at the same pressure. This balance ensures the accuracy of downstream air and oxygen blending.

In the event air is lost, the Crossover Solenoid opens, delivering high pressure oxygen to the Air Regulator, which in turn regulates the O₂ Relay.

BLENDER

Air and oxygen enter the Blender and mix to the desired oxygen concentration selected by the O₂% control on the ventilator front panel. The Bleed Solenoid bleeds a small constant flow from the blender, to ensure accurate blending at low flow rates.

In the event of a GAS SUPPLY FAILURE alarm, caused by a drop in air or oxygen supply pressure (to below 27.5 psig), the Blender switches over completely to the remaining gas supply. Either 100% oxygen or 100% air (i.e., 21% oxygen) is supplied to the patient.

WARNING

When a GAS SUPPLY FAILURE alarm occurs, the Blender will use the remaining gas supply. This means that the oxygen concentration delivered to the patient may differ from the clinician-selected O₂ setting.

If an error is detected in the Blender during a power-up, a RUN DIAGNOSTICS alarm activates both audibly and visually.

ACCUMULATOR

Blended gas leaves the Blender and enters the rigid 3.5 liter Accumulator. Under both low- and no-output-flow conditions, the mixed gas from the Blender fills the accumulator until it reaches system pressure (18.0 psig). In response to an output flow demand, the stored volume in this Accumulator is supplied to the Flow Control Valve, thereby reducing the instantaneous flow demand imposed on the Blender. This minimizes flow-generated pressure transients upstream, and thus maintains stable O₂ concentrations at the Blender output.

The Accumulator has two important functions:

- It acts as a mixing chamber for the blended gas, resulting in increased stability of the oxygen concentration.
- It allows for high peak output flows of over 200 LPM while only requiring a relatively low (80 LPM) gas input from the wall.

FLOW CONTROL VALVE

Blended gas from the Accumulator enters the Flow Control Valve (FCV) at 10–18 psig of pressure. This inlet pressure varies due to the gas storage function of the Accumulator.

Both ventilator control settings and patient demand together determine the output flow from the FCV.

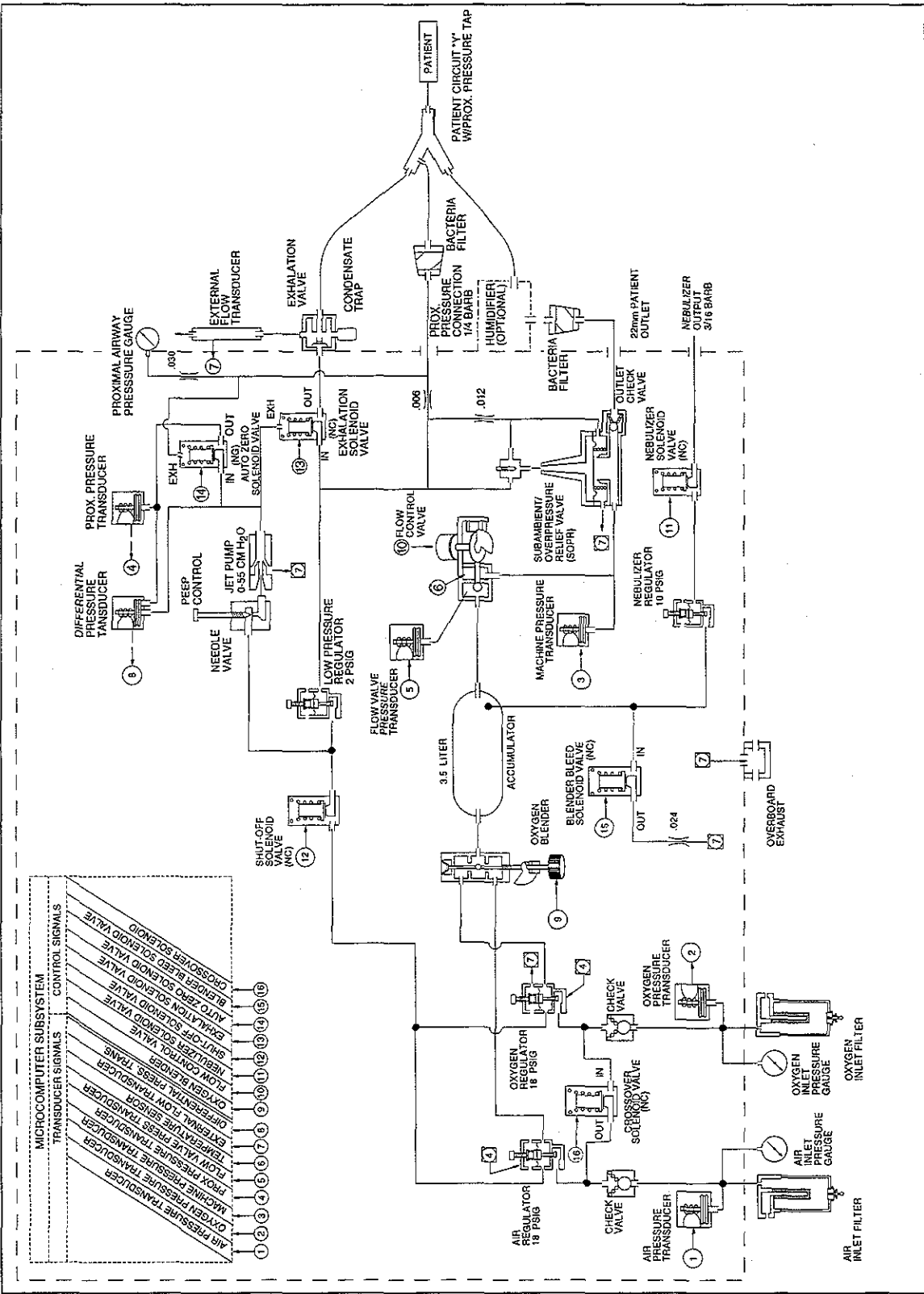


Figure 2-2

Whatever the output flow established by the flow delivery logic, the temperature sensor built into the FCV enables the ventilator to deliver accurate volumes based upon a standard temperature correction, 77°F, zero saturation and the set barometric pressure.

The FCV delivers peak flows in the range of:

Volume-controlled Breaths: 10 to 150 LPM

Demand or Pressure Breaths: 0 to over 200 LPM

SOPR VALVE

From the FCV, the gas flows through the Subambient Overpressure Relief Valve (SOPR) and out of the ventilator through the port labeled "Main Flow to Patient."

During normal operation, the Low Pressure Regulator supplies 140 cmH₂O to the SOPR valve diaphragm, thereby closing its relief port. Because this port is closed, gas from the FCV passes directly through the SOPR and out to the patient.

When the Fail State System activates (due to a FAILED TO CYCLE alarm or a power failure),

the 140 cmH₂O normally supplied to the SOPR valve diaphragm falls to zero, and the SOPR relief port opens. When the relief port opens, the patient can breathe room air.

Beside providing the patient with access to room air, the SOPR has a second function. It acts as an independent relief valve to mechanically limit the maximum pressure the ventilator can deliver. This mechanical limit functions only when ventilator outlet pressure exceeds 175 cmH₂O. Such a high pressure on the front side of the SOPR relief port causes the port to open and thereby relieve excess gas through the outlet labeled "Overboard Exhaust."

LOW PRESSURE CONTROL SYSTEM

The Low Pressure Control (LPC) System serves three functions:

- It provides 140 cmH₂O to the SOPR valve diaphragm, and
- It controls the Exhalation Valve Diaphragm to determine breath phase (inspiration vs. exhalation) and PEEP level,
- It supplies gas to the Proximal Purge.

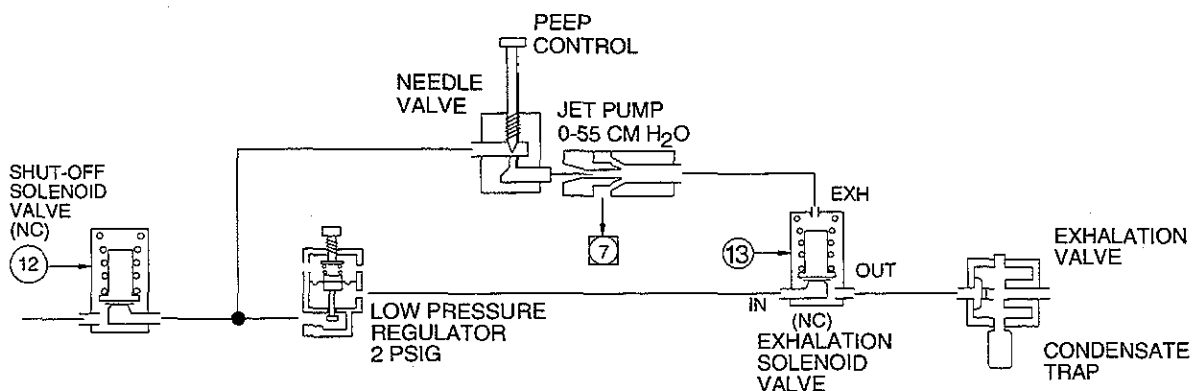


Figure2-3 • Low Pressure Control System

The LPC System consists of the following components:

- Shut-off Solenoid Valve
- Low Pressure Regulator
- PEEP Needle Valve
- PEEP Jet Pump
- Exhalation Solenoid Valve

After entering the ventilator and passing through the regulator, air is tapped off before entering the Blender. This sidestream of 18 psig gas feeds directly into the Shut-off Solenoid Valve.

During normal operation, the Shut-off Solenoid Valve is energized, passing 18 psig gas from the Gas Inlet System to both the Low Pressure Regulator and the PEEP Needle Valve. Under this circumstance, the LPC System functions as follows:

1. SOPR Valve: The 140 cmH₂O from the Low Pressure Regulator enters the SOPR valve diaphragm, thereby holding its relief port closed.
2. Exhalation Valve and PEEP Control: The Exhalation Solenoid Valve switches the reference pressure for the Exhalation Valve Diaphragm between:
 - The 140 cmH₂O supplied by the Low Pressure Regulator, and
 - The output pressure from the combination of the PEEP Needle Valve and the PEEP Jet Pump.

This allows the Exhalation Valve to close during inspiration and maintain PEEP during exhalation.

By contrast, during Fail State Operation (a FAILED TO CYCLE alarm or a power failure), the LPC System functions as follows:

1. SOPR Valve: The Shut-off Solenoid Valve de-energizes and closes. This cuts off the pneu-

matic drive to the Low Pressure Regulator which in turn, cuts off gas pressure to the back side of the SOPR Valve, thereby causing its relief port to open, and allowing the patient to inhale room air.

2. Exhalation Valve and PEEP Control: The closing of the Shut-off Solenoid Valve deprives the PEEP Needle Valve of drive pressure. The PEEP Jet Pump consequently exhausts all pressure applied to the Exhalation Valve. Because the Exhalation Valve is also de-energized by the Fail State System, it references this zero PEEP pressure being supplied by the PEEP Needle Valve and Jet Pump. As a consequence the Exhalation Diaphragm opens completely, allowing the patient to exhale, unimpeded.

EXHALATION VALVE

The Exhalation Valve regulates all flow out of the patient circuit. Exhaled patient gases flow through the expiratory leg of the patient circuit, past the Exhalation Valve Diaphragm and Seat, and through the External Flow Sensor. The Exhalation Valve is designed to minimize pressure fluctuations as well as audible noise.

The pressure required to:

- Close the Exhalation Valve during a positive pressure inspiration and
- Control the baseline (PEEP) pressure

The Exhalation Valve also acts as a check valve so the patient cannot rebreathe gas through the expiratory leg of the circuit.

A condensate jar attached to the Exhalation Valve Manifold collects condensed water from the circuit and manifold.

EXTERNAL FLOW SENSOR

The External Flow Sensor, connected to the Exhalation Valve Manifold, measures exhaled

tidal volumes. The flow sensor operates on the principle of hot wire anemometry.

The hot wire flow sensing system is a constant temperature device. The unidirectional operation is achieved with the two platinum wires as follows:

- A reference wire monitors the ambient gas temperature and communicates this temperature to the sensor electronics.
- A hot wire is held at a constant high temperature level based upon the temperature feedback from the reference wire.

The rate of heat loss from the hot wire varies directly with the velocity of the exhaled gases as they pass through the flow sensor. As the gas flow rate increases, the electronic circuitry applies additional electrical current to the wire to maintain a preset temperature. The resulting voltage change can then be translated into a gas flow rate. This measured flow rate is then integrated over time by the ventilator's microprocessor to yield the measures of exhaled volumes which are displayed on the front panel monitors.

NEBULIZER SYSTEM

When the NEBULIZER key on the ventilator control panel is activated, the Nebulizer Regulator and Nebulizer Solenoid Valve together allow nebulization during the inspiration phase of any breath type so long as flow exceeds approximately 20 LPM. Thus nebulizing is synchronized with patient breathing.

The Nebulizer Regulator reduces the 18 psig pressure from the Accumulator to 10 psig.

While the solenoid valve is open, 6 LPM is assumed to flow through the nebulizer (the actual amount depends upon the specific nebulizer being used.) This 6 LPM is subtracted from the flow delivered by the FCV. In this manner the overall flow (nebulizer plus Main

Flow output port) and volume are maintained at the clinician-set levels.

The oxygen concentration of the nebulizing gas is the same as that on the O₂% control.

VENTILATOR ELECTRONICS

The five major components the Monitor PCB, the Control PCB, the Electro-Pneumatic Interface (EPI) PCB, the Flow Sensor PCB, and the Power Supply

ELECTRONICS

Monitor PCB & Control PCB

The user operates the ventilator through the front panel controls and displays.

The Monitor and Control PCBs constantly scan the front panel for current settings or for clinician-generated changes. If an appropriate membrane key is selected, the Monitor and Control PCBs couple this parameter to the control knob. An optical encoder senses knob rotation and increases or decreases the currently displayed value accordingly.

The Monitor and Control PCBs receive patient and machine status information from the Electro-Pneumatic Interface (EPI) PCB. Based on clinician-selected control settings and EPI feedback, algorithms within the Control PCB calculate the required delivered gas flow, O₂ concentration, and Exhalation Valve state. The Control PCB transmits this information to the EPI PCB, which executes changes to the appropriate electro-mechanical devices.

Another major function of the Monitor and Control PCBs is to monitor and display the ventilator's clinical data. When monitored parameters deviate beyond clinician-set alarm limits, the Monitor and Control PCBs create audible and visual alarms.

The Control PCB also has an RS-232 9-pin digital communication port to communicate continuous real time control, monitor and alarm data to external devices. The RS-232 communication port transmits data either to the optional BEAR® Graphics Display, or a computer. (For a detailed description of the protocol, refer to the BEAR® 1000 Instruction Manual.) There is also a 15-pin analog port for use in obtaining real time outputs of pressure, flow and volume signals as defined in the Analog Outputs.

ELECTRONICS

EPI & Flow Sensor PCB

The major purpose of the EPI is to provide an interface between the Control PCB and the pneumatic hardware. The EPI receives the desired flow, oxygen concentration, and solenoid valve states every 10 milliseconds from the Control PCB. Based on this information, the EPI commands the individual electro-mechanical components to move to their correct positions.

The second function of the EPI is to read the various transducer outputs, digitize the data and transmit it to the Control PCB for processing. Six pressure transducers, mounted on the EPI monitor: Proximal Airway Pressure, Machine Pressure, Proximal/ PEEP Differential Pressure, Flow Control Valve Pressure, and Air and Oxygen Supply Pressures. The EPI also interfaces with a temperature sensor and the Flow Sensor PCB, to measure delivered gas temperature and exhaled flow, respectively.

In addition to the various transducers, the Autozero Solenoid is also mounted on the EPI. During power up *only*, the Autozero Solenoid valve is briefly energized (opened). During this time, the solenoid is used to zero the Proximal/PEEP Differential Pressure Transducer.

ELECTRONICS

Fault Detection

The BEAR® 1000 Ventilator, through its own operating hardware and software, continuously monitors itself for subsystem failures. Depending upon the type of failure detected, one of two states will occur:

- Alarm State: an alarm activates to alert the operator of the failure, nevertheless ventilation continues; or
- Fail State: the system activates the "Fail State" system; the ventilator ceases to operate, but the patient is allowed to breathe room air and exhale unimpeded.

If the Fail State activates:

1. All solenoids de-energize. The Shutoff Solenoid removes pneumatic drive pressure to the SOPR Valve diaphragm, PEEP Needle Valve and Exhalation Diaphragm Solenoid Valve, thereby opening the SOPR and Exhalation Valves to atmospheric pressure. The Exhalation Diaphragm Solenoid sets the Exhalation Valve reference pressure to zero. The Nebulizer Solenoid shuts off all nebulizer flow.
2. The EPI closes the Flow Control Valve electronically to prevent additional gas from being delivered to the patient.
3. The patient has access to room air through the SOPR valve.

The BEAR® 1000 Ventilator has three independent mechanisms for detecting these failures in the system:

1. Control PCB Detected Failures
2. EPI PCB Detected Failures
3. Loss of DC Power

ELECTRONICS

Power Supply

The Power Supply converts AC line voltage to DC voltages for the electrical system. If there is a temporary AC line power failure, the Power Supply provides DC power until the voltage in the capacitors drops to below 20.4 VDC. This residual voltage provides more than 300 milliseconds of continuing operation, allowing for alarm-free operation during the most common types of electrical power failure.

Once the voltage in the capacitors reaches 20.4 VDC, the Power Supply causes the ventilator to enter the Fail State, and the following occurs:

1. The alarm sounds for a minimum of 5 minutes.

2. The Flow Control Valve closes and the SOPR valve opens to allow the patient to breathe room air.

NOTE: PEEP is not maintained.

3. The ventilator power shuts off.

Once the Flow Control Valve is closed, +5 VDC is left for the ECS and EPI microprocessors, which continue to run until the +5 VDC is lost. This provides enough power for the microprocessors to store any troubleshooting codes to the EEPROM for later review.

FLOW DELIVERY LOGIC

The logic controlling the flow delivered by the FCV physically resides on the Control PCB. The logic is composed of two parts: Volume Logic and Pressure Logic.

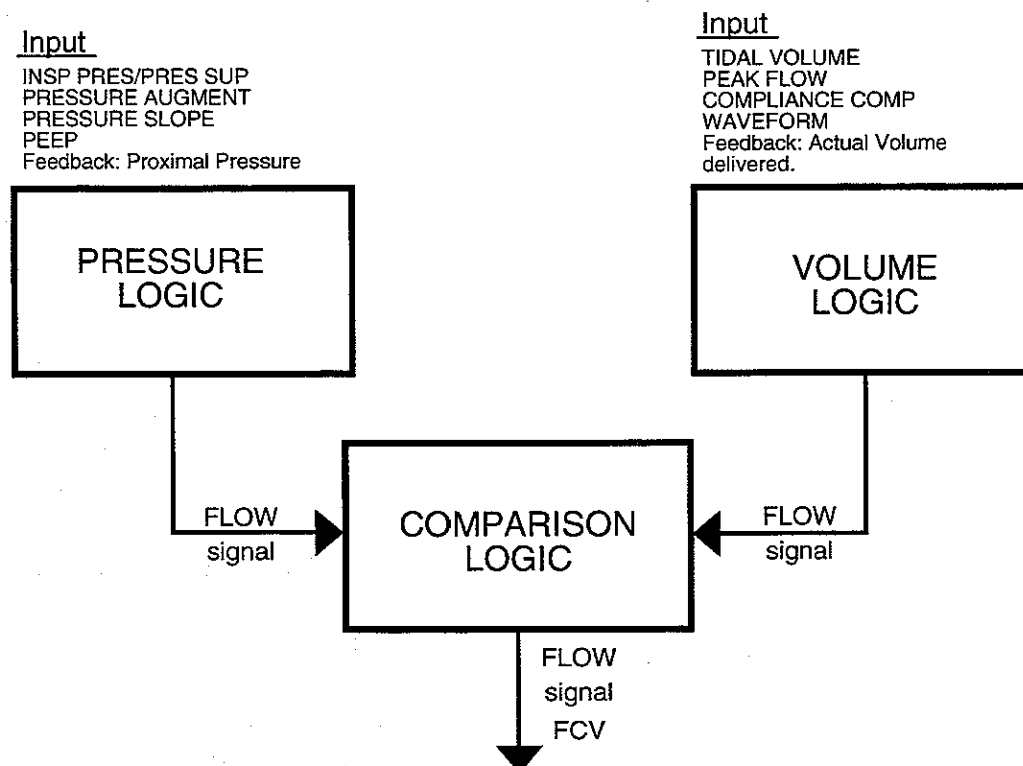


Figure 2-4 • Flow Delivery Logic

The Volume Logic determines how much flow should be provided by the FCV to achieve volume-controlled breaths. At the same time, the Pressure Logic determines how much flow should be provided by the FCV to achieve:

- All pressure breaths, including pressure-supported, pressure-controlled, and pressure-augmented;
- All demand breaths, including spontaneous breaths, flow and volume augmentation and leak makeup.

As suggested, the capability called the "Demand System" resides within the Pressure Logic of the BEAR® 1000 Ventilator.

Figure 2-4 shows how two messages (one from the Volume Logic and the other from the Pressure Logic) are compared by the "Comparison" Logic. The "Comparison" Logic then sends the larger of the two messages to the FCV which implements flow delivery.

VOLUME LOGIC

When a patient passively receives a volume-controlled breath, the Volume Logic uses the preset TIDAL VOLUME, PEAK FLOW, and WAVEFORM to calculate a flow signal that is sent to the "Comparison" Logic.

Because this is a passively-received breath, the Pressure Logic sends a zero flow signal to the "Comparison" Logic. The "Comparison" Logic then compares these two signals and sends the larger one (which in this case is the Volume flow signal) to the FCV.

The Volume Logic uses feedback information from the FCV regarding actual delivered volume to determine when to switch to sending a "zero flow" signal to the "Comparison" Logic. This occurs when the TIDAL VOLUME and the optional COMPLIANCE COMP volume have been delivered.

PRESSURE LOGIC

Demand breaths rely solely upon the Pressure Logic to determine the flow output from the FCV.

When a patient initiates a demand breath, proximal airway pressure drops below baseline. The Pressure Logic (in the Control PCB) sends a signal through the "Comparison" Logic to the FCV instructing it to respond with sufficient flow to maintain proximal airway pressure at either:

- PEEP (for spontaneous breaths), or
- PRES SUP/INSP PRES plus PEEP (for pressure-supported breaths).

For spontaneous or pressure-supported breaths the Pressure Logic drops its flow message to zero once delivered flow drops to approximately 30% of the peak inspiratory flow.

Pressure Control Breaths

The flow delivery logic for a pressure-controlled breath is similar to that of a pressure-supported breath except that:

- The breath trigger can be machine-controlled, as well as patient controlled, and
- The end of inspiration is determined by the clinician-set INSPIRATORY TIME control rather than by a drop in flow.

Pressure Slope

The PRESSURE SLOPE control affects the rate at which the flow signal increases to its peak value. In essence it operates through the Pressure Logic to determine how fast the FCV opens. Thus it affects how slowly or rapidly the preset inspiratory pressure level is achieved at the airway.

Flow and Volume Augmentation

The goals of flow and volume augmentation are to:

1. Ensure that the patient is never starved of flow, and
2. Reduce stacking of volume breaths (auto-cycling).

To achieve these goals, delivered flows must meet or exceed patient demand. To begin with, the Volume Logic begins to deliver a volume-controlled breath according to the clinician-selected PEAK FLOW, WAVEFORM, and TIDAL VOLUME settings. Then, if the patient demands more flow than that delivered by the Volume Logic, proximal airway pressure drops. When pressure drops below baseline, the Pressure Logic sends a signal to increase flow beyond the flow signal from the Volume Logic to maintain airway pressure at baseline.

This increase in flow is termed "flow augmentation."

If the patient continues to demand flow even after the clinician-set TIDAL VOLUME has been delivered, the Volume Logic will start sending a "zero flow" signal to the "Comparison" Logic. However, the Pressure Logic will continue to request flow to meet patient demand and to maintain pressure at baseline. The "Comparison" Logic, as usual, chooses the larger of these two flow signals (that from the Pressure Logic) and sends the flow signal to the FCV. When patient demand for flow drops to approximately 30% of its peak value, the Pressure Logic switches to a "zero flow" signal, and the FCV stops delivering flow. The patient receives a larger tidal volume than set on the controls because the patient has demanded a larger volume. The increase in tidal volume is termed "volume augmentation."

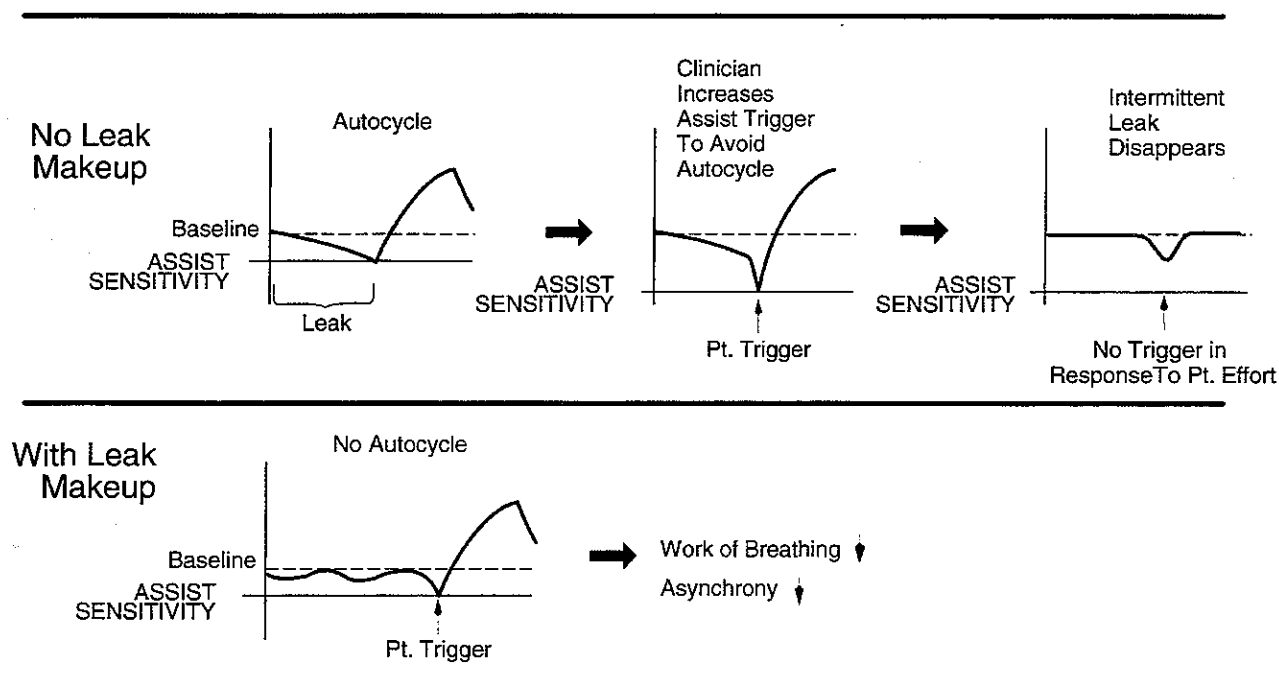


Figure 2-6 • Leak Makeup

Pressure Augmentation

Pressure augmentation provides additional pressure support beyond that provided by flow augmentation. Accordingly, with pressure augmentation, the patient is likely to perform even less work during a volume-controlled breath.

The flow delivery logic behind pressure augmentation is similar to flow augmentation except that the Pressure Logic ensures that proximal airway pressure never drops below the sum of:

$(PEEP + PRES\ SUP/INSP\ PRES)$

Accordingly, relative to flow augmentation, pressure augmentation causes the Pressure Logic to increase flow higher, thereby further unloading the active patient's ventilatory muscles.

Leak Makeup

During exhalation, a "leak" in the patient circuit can cause baseline pressures to drop. The Pressure Logic recognizes the drop in proximal airway pressure and sends a signal to the FCV (through the "Comparison" Logic) to increase flow until the proximal airway pressure returns to the PEEP level. This process is termed "leak makeup."

Section 3

BEAR® 1000 Ventilator

Operational Verification Procedure

Operational Verification Procedure.....	1
Test Equipment	1
Exterior Inspection and Cleaning.....	2
Cleaning	2
Filters	2
Plugs and Cables	2
Automated Built-in Diagnostics	3
Test Setup	4
Entering Operator Diagnostics	4
Display Panel Verification.....	4
Manual Testing	5
Air/O ₂ Inlet Check Valve Verification.....	7
Air/O ₂ Inlet Pressure Gauge Verification	7
Alarm Loudness Testing	7
Breath Rate Verification	8
Oxygen Blending Verification	8
Assist Sensitivity Verification	9
Delivered/Exhaled Volume Verification.....	10
Power Loss Test.....	10
Appendix A.....	11
Checklist.....	13
Active Functions and Displays for Operator Diagnostics	14

OPERATIONAL VERIFICATION PROCEDURE

(Operator Diagnostics)

This procedure is to assist a Qualified Operator, Hospital Service Technician, or Bear Medical Systems Service Technician ensure that the BEAR® 1000 Ventilator is in proper operating condition. A checklist is included and should be completed during each operational verification. A copy of the checklist should be maintained in the hospital file. The attached checklist may be copied, providing forms for future use.

VERIFICATION PROGRAM

The Operational Verification Procedure (OVP) is divided into two parts.

Part 1 consists of an automated series of built-in diagnostics tests and should be performed at least monthly.

Part 2 consists of additional manual verifications and should be performed at least twice a year.

Do not use the ventilator unless it passes the Operational Verification Procedure. For servicing, contact a Bear Medical Systems Service Technician or a Bear Medical Systems Trained Hospital Technician.

OPERATIONAL VERIFICATION PROCEDURE

The following verification procedure should be performed in the hospital by a Qualified Operator, Hospital Service Technician, or a Bear Medical Systems Service Technician. Familiarity with the function, set-up and operation of the BEAR® 1000 Ventilator is assumed. (See BEAR® 1000 Ventilator Instruction Manual.) Perform all tests in the following sequence.

WARNING

The Operator Diagnostics must never be performed when the ventilator is connected to a patient. To do so could result in serious injury to the patient.

NOTE

The use of test equipment not specified will introduce variables which may influence test results. Do not assume that a failure has occurred if the specified test equipment or its equivalent is not used.

TEST EQUIPMENT SPECIFIED FOR THE OVP

Tube, Circle 72" x 3/4 (2 ea.)51000-02759*
 Patient Wye51000-01104*
 Chamber, VH-820.....51000-02739*
 Filter, Proximal Line.....50000-01106*
 Filter, Mainflow51000-01054*
 Tubing, PVC, 1/4" ID, 72"
 Plug for Patient Wye
 Plug for Humidifier Water Port
 Oxygen Analyzer, 1% Accuracy
 Pressure Gauge, 0-100 psi $\pm 1\%$ F/S or better—Ametek
 Model 1903, Ashcroft type 1279, or equivalent
 Pressure Gauge, 0-10 cmH₂O $\pm 1\%$ F/S—
 Marshalltown Model 86F, with scale in cmH₂O,
 Wallace & Tiernan Model FA 14170 or equivalent
 Timer RT-200 or equivalent
 Test Lung, R5, C10
 Regulated Air/O₂ Source
 Shut Off Valves
 Stopwatch

*(or equivalent)

WARNING

The following warnings must be read and understood before performing the procedures described in this section.

Under no circumstances should this medical device be operated in the presence of flammable anesthetics or other volatile materials due to a possible explosion hazard.

Liquid spilled or dripped into the unit may cause damage to the unit or result in an electrical shock hazard.

Oxygen vigorously accelerates combustion. To avoid violent ignition, do not use any gauges, valves, or other equipment that has been exposed to oil or grease contamination.

Do not release this medical device if any alarm/alert function is inoperative. To do so could result in a malfunction without warning, possibly resulting in personal injury up to including death or property damage. Refer the unit to a Bear Medical Systems Authorized Service Technician or a Bear Medical Systems Trained Hospital Service Technician.

WARNING

All tubing and fittings used to connect high pressure gas (air and oxygen) from the source to the test equipment and from the test equipment to the device being tested must be capable of withstanding a minimum supply pressure of 100 psi (7.03 kg/cm²). The use of tubing and fittings not capable of withstanding this pressure could cause the tubing to rupture, resulting in personal injury or property damage.

When verifying the operation of this medical device, do not breathe directly from the machine. Always use a fresh bacterial filter and test circuit. A hazard to the health of the service person may result.

If any of the following procedures cannot be verified as outlined in this document, do not use this device on a patient and refer it to Bear Medical Systems or a Bear Medical Systems Authorized Service Facility or a Bear Medical Systems Trained Hospital Service Technician.

CAUTION

The following cautions must be read and understood before performing the procedures described in this section.

Do not use MEK or Trichloroethylene, as damage to surface may result. Do not allow any liquid to spill or drip into the ventilator.

Do not gas sterilize the ventilator. The internal materials are not compatible with gas sterilization techniques.

Before using any test equipment [electronic or pneumatic] for calibration procedures [other than operational verification], the accuracy of the instruments must be verified by a testing laboratory. The laboratory master test instruments must be traceable to the NIST (National Institute of Standards Technology) or equivalent. When variances exist between the indicated and actual values, the calibration curves [provided for each instrument by the testing laboratory] must be used to establish the actual correct values. This certification procedure should be performed at least once every six months. More frequent certification may be required based on usage and environment.

EXTERIOR INSPECTION AND CLEANING

Inspect all cords, connectors, and fittings. Inspect the case for any cracks or other damage.

CLEANING

1. Before any cleaning of the ventilator, disconnect WALL A.C.
2. Clean the exterior of the ventilator with an appropriate bactericidal or germicidal agent. Care should be exercised not to allow any liquid to penetrate the inside of the ventilator.

CAUTION

Do not gas sterilize or steam autoclave the ventilator.

FILTERS

The cabinet air inlet filters are easily accessible for removal and cleaning. The filters may be vacuumed or washed in warm soapy water, rinsed, and thoroughly dried.

CAUTION

Do not operate the ventilator without the filters in

PLUGS AND CABLES

Plugs and cables may be wiped down with an appropriate bactericidal or germicidal agent.

PART 1

Automated Built-In Diagnostics

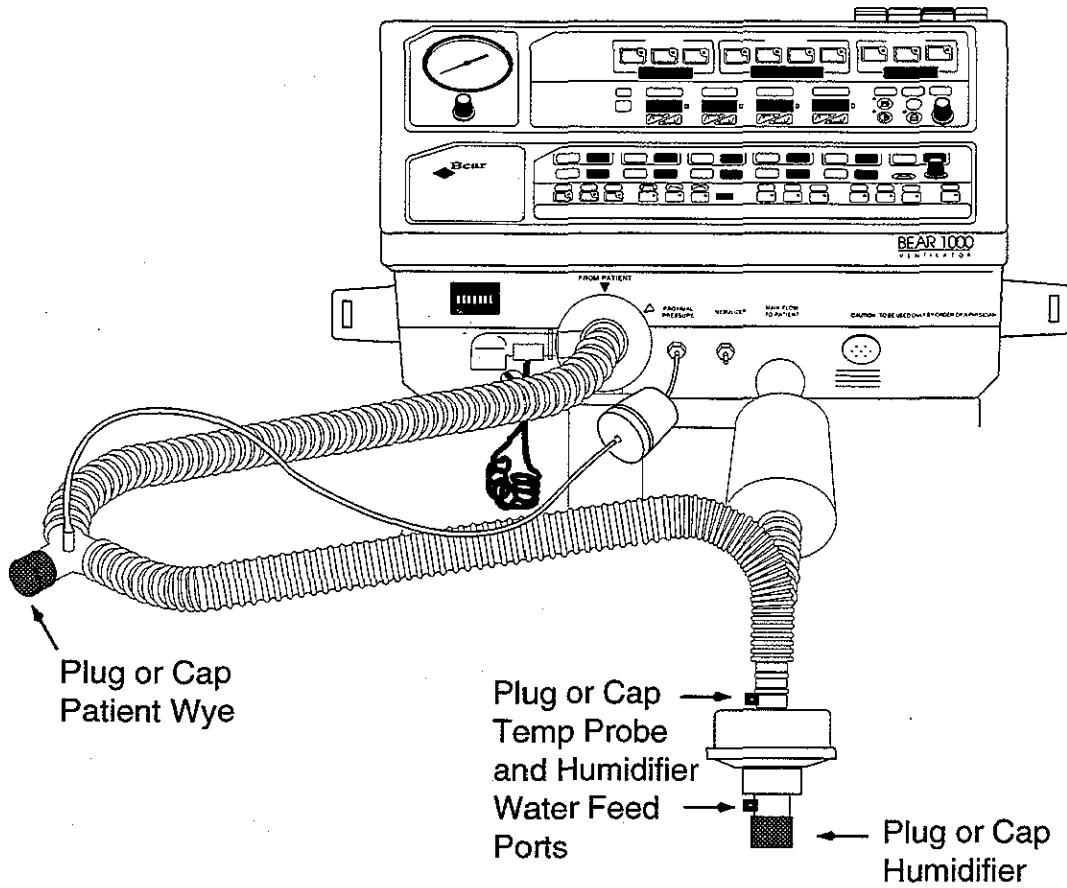


Figure 3-1
Patient Circuit Connection

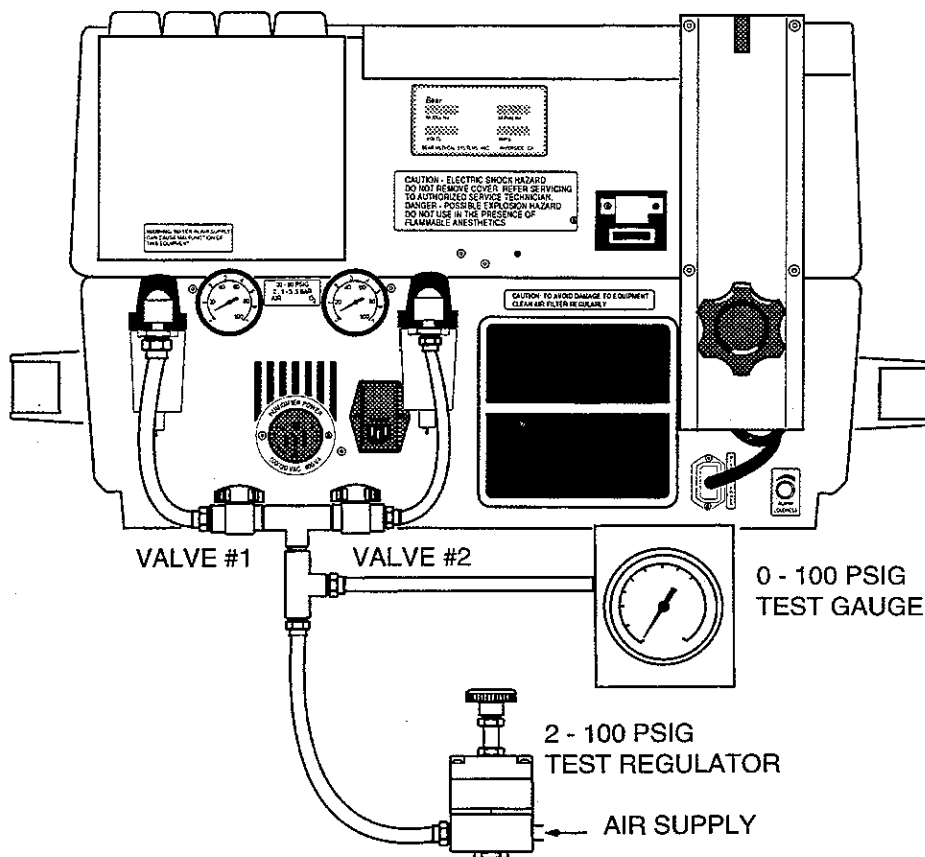


Figure 3-2
External Gas Source Connections

TEST SETUP

1. Connect the test circuits to the ventilator as shown in Figures 3-1 and 3-2.
2. Plug the open end of the patient wye and the water inlet port of the humidifier.
3. Record the reading from the Hourmeter on the checklist.

NOTE

While the Operator Diagnostics are in operation, there will be other information displayed in the displays. These are not part of the Operator Diagnostics. For an explanation of these values, see Appendix A.

NOTE

The keyboard is redefined in Diagnostics. See Figure 3-9 for these functions.

NOTE

Turn the Graphics Display OFF when running the Diagnostic tests. If the Graphics Display is on, false d2 failures may occur.

ENTERING THE OPERATOR DIAGNOSTIC MODE

NOTE

PEEP must be turned off completely prior to entering the Diagnostic Mode to avoid test failure. Be sure the PEEP control is set completely counter clockwise.

1. With the ventilator power off, depress and hold the TEST Key.
2. Turn on the ventilator power and hold the TEST Key down until the Power On Testing is complete (approx. 20 seconds).
3. While the Power On tests are running, observe that all digital displays and LEDs light.
4. When the Power On Test is complete, observe and record the Configuration Code shown in two of the displays in the Controls section (See Figure 3-9). Verify that the displayed Code matches the Configuration Code on the rear of the ventilator.

5. Select one of the following tests by pressing the Test Number Key and rotating the SET knob. The selection will appear in the Test Number display window.

- a. All All Diagnostic Tests (d 1 through d 7)
- b. d 1 Power Up Diagnostics
μ Processor Self Check
ROM Check Sum
RAM Test
- c. d 2 Flow Control Valve Test
- d. d 3 Blender Control Valve Test
- e. d 4 Leak Test
- f. d 5 Flow Delivery/
External Flow Testing
- g. d 6 SOPR System Test
- h. d 7 Pressure Delivery/
Pressure Sensing Test

6. The tests may be run in three different ways by pressing the following keys:

- a. Run Test Once
Runs the selected test one time.
- b. Cycle Test
Runs the selected test until it is cancelled or a failure occurs.
- c. Cancel Test

Halts the running of diagnostics at the end of the current test.

NOTE

Due to the extensive nature of the RAM test, Diagnostic d1 takes approximately 80 seconds to complete.

NOTE

While a test is in progress, characters will be seen rapidly flashing in the Test Results display window indicating the test is in progress.

7. When a test has been successfully completed, a "P" will appear in the Test Results window.
8. If a test fails, an "F" will appear in the Test Results window.

9. Turn off ventilator to exit Diagnostic mode.

PART 2

MANUAL TESTING

Table 1—Standard Settings

PEEP Pressure.....	0 cmH ₂ O
Alarm Settings	
* I:E Override.....	ON
High Total Minute Volume	80 L
Low Total Minute Volume	0.0 L
High Total Breath Rate.....	155 BPM
Low Total Breath Rate.....	3 BPM
High Peak Insp Pressure	120 cmH ₂ O
Low Peak Insp Pressure	3 cmH ₂ O
* High Baseline Pressure.....	55 cmH ₂ O
* Low Baseline Pressure	0 cmH ₂ O
Control Settings	
Tidal Volume	0.5 L
Breath Rate.....	10 BPM
Peak Flow	65 LPM
% Oxygen	21 %
Pres Sup/Insp Pres	0 cmH ₂ O
Assist Sensitivity	5.0 cmH ₂ O
* Inspiratory Pause	0.0 sec
* MMV Level	0 LPM
* Compliance Comp	0.0 mL/cmH ₂ O
* Inspiratory Time.....	1.0 sec
* Pressure Slope	0
Mode	SIMV/CPAP
Waveform.....	Square
* 100% Oxygen.....	Off
* Sighs.....	Off
* Pressure Augment.....	Off
Nebulizer	Off

* Not applicable for Bear® 1000 Basic Unit.

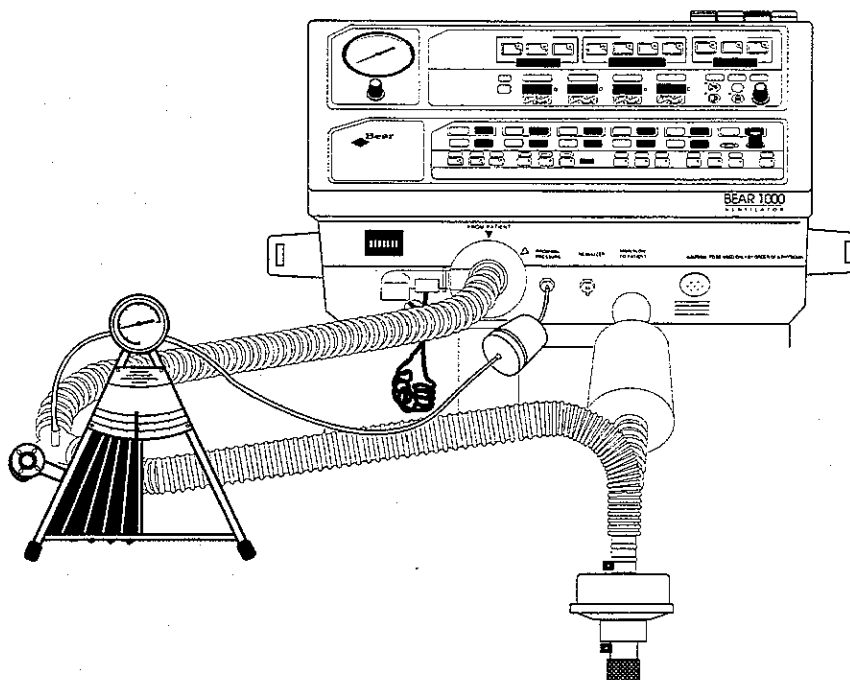


Figure 3-3

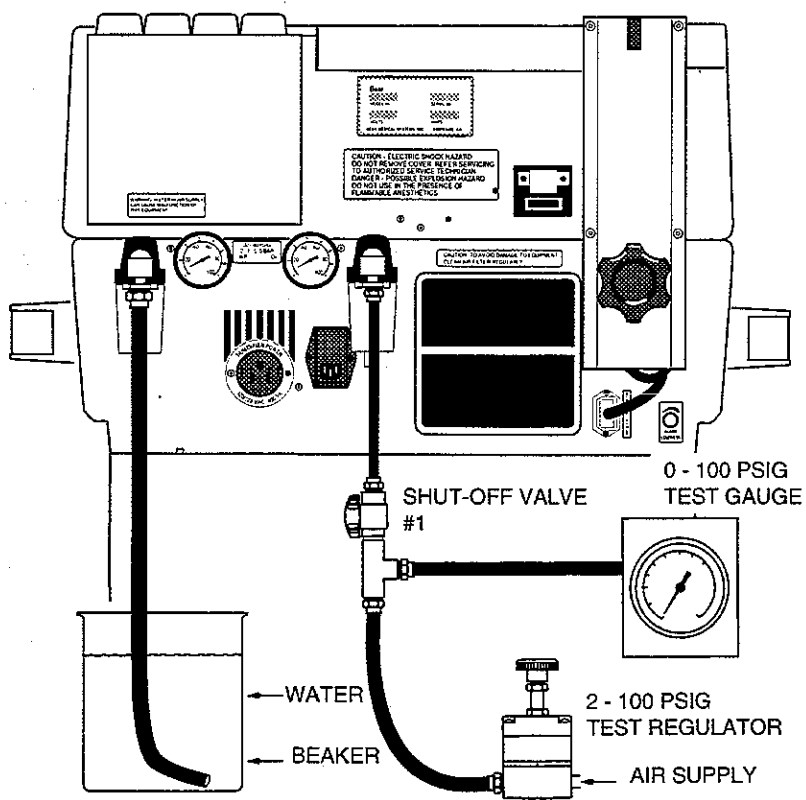


Figure 3-4

AIR/O₂ INLET CHECK VALVE VERIFICATION

1. Connect the ventilator as shown in Figure 3-3.
2. Adjust the controls as shown in Table 1 except change the Oxygen % to 60%.
3. Connect the ventilator as shown in Figure 3-4.
4. Close Valve No.1.
5. Adjust the 100 psi regulator for an indication of approximately 50 psi on the test gauge.
6. Turn ON the ventilator power, ignore any alarms.
7. Open valve No.1.
8. Verify that there is no release of bubbles from hose submerged in beaker of water.
9. Close Valve No.1 and connect the test gauge, regulator and shut-off valve to the air inlet. Connect the hose and beaker to O₂ inlet. Repeat Steps 7 and 8.
10. Turn the regulator down to zero and close Valve No.1.
11. Turn the ventilator power OFF, and repeat the procedure with the power turned OFF.
12. Check the appropriate block on the OVP checklist.

IR/O₂ INLET PRESSURE GAUGE VERIFICATION

1. Connect the ventilator as shown in Figure 3-5.
2. Sequentially apply 10, 30, and 50 psig.
3. Verify that at each pressure the inlet gauges indicate ± 5 psig of the applied pressure.
4. Change Oxygen % to 21%.
5. Close valve #2.
6. Verify that the Gas Supply failure alarm doesn't come on.

ALARM LOUDNESS TESTING

1. Set the ventilator as shown in Table 1.
2. Create any condition that will cause a ventilator alarm (i.e. Pressure limit).
3. While the alarm is sounding, adjust the alarm loudness control on the rear of the ventilator.
4. Verify that the alarm loudness can be varied but not turned completely off.
5. Reset alarm to original setting or new setting if desired.

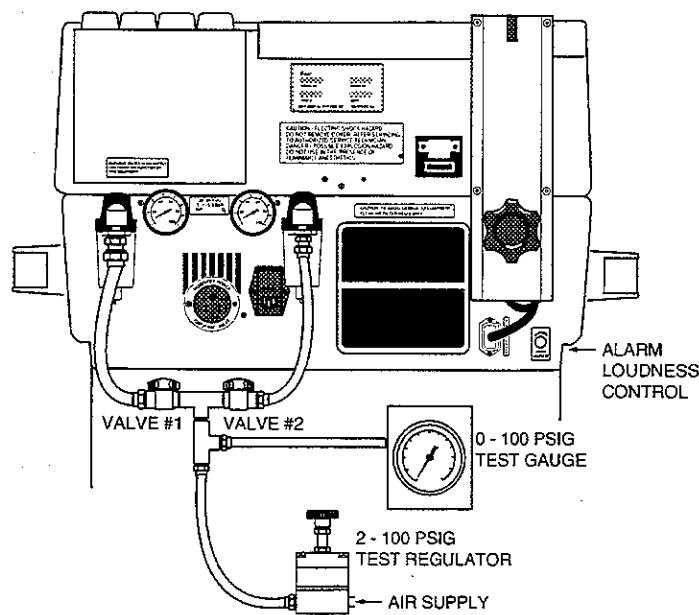


Figure 3-5

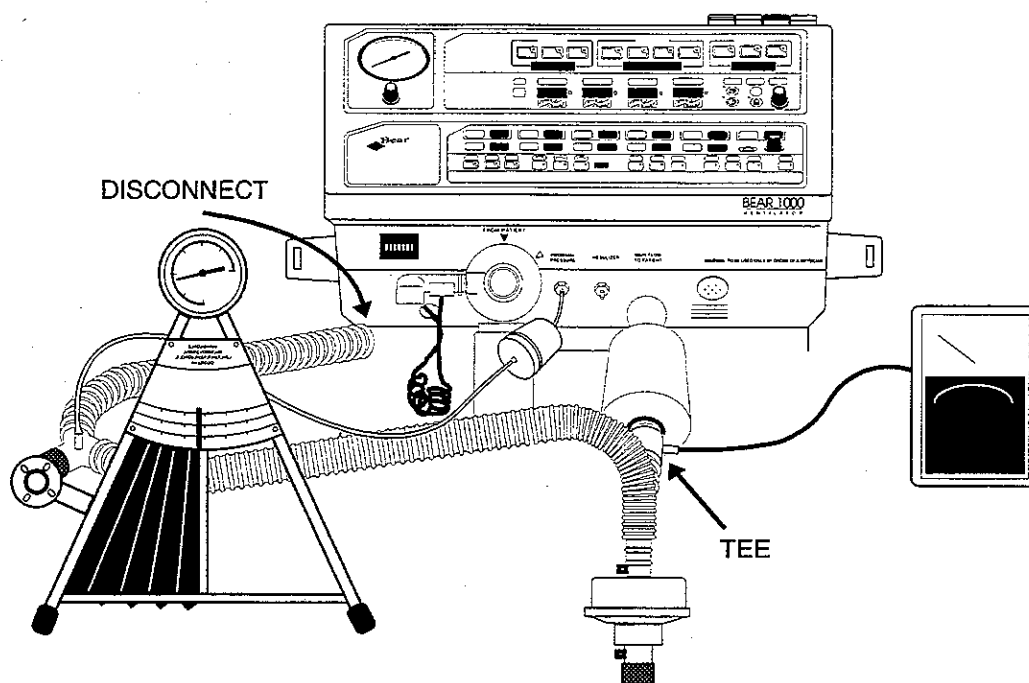


Figure 3-6

BREATH RATE VERIFICATION

1. Set the ventilator as shown in Table 1.
2. Allow the ventilator to cycle and using a stopwatch, verify the following rates ± 2 BPM:
 - a. 6 BPM
 - b. 60 BPM
6. Disconnect the oxygen source and reconnect the air source.
7. Return the ventilator to the settings shown in Table 1.

OXYGEN BLENDING VERIFICATION

1. Refer to Figure 3-2; close valve 2 and disconnect the hose.
2. Connect an O₂ supply and apply pressure.
3. Set the ventilator as shown in Table 1, but set the breath rate at 25 BPM.
4. Connect an oxygen analyzer in line with the patient circuit as shown in Figure 3-6.
5. Vary the ventilator settings as shown in Table 2 and verify that the results agree with the specifications.

Table 2—Oxygen Blending Settings

O ₂ %	Tidal Volume	Breath Rate	Peak Flow	Specification
21%	0.50L	25	30	20 to 25%
40%	0.10	50	30	36 to 44%
40%	0.50	25	30	36 to 44%
60%	0.10	50	30	56 to 64%
60%	0.50	25	100	56 to 64%
80%	0.10	50	30	76 to 84%
80%	0.50	25	30	76 to 84%
100%	0.50	25	30	96 to 100%

NOTE

Due to a 3.5 liter accumulator chamber within the ventilator, oxygen percentage changes will not be immediate. Allow time for stabilization to occur before verifying specifications.

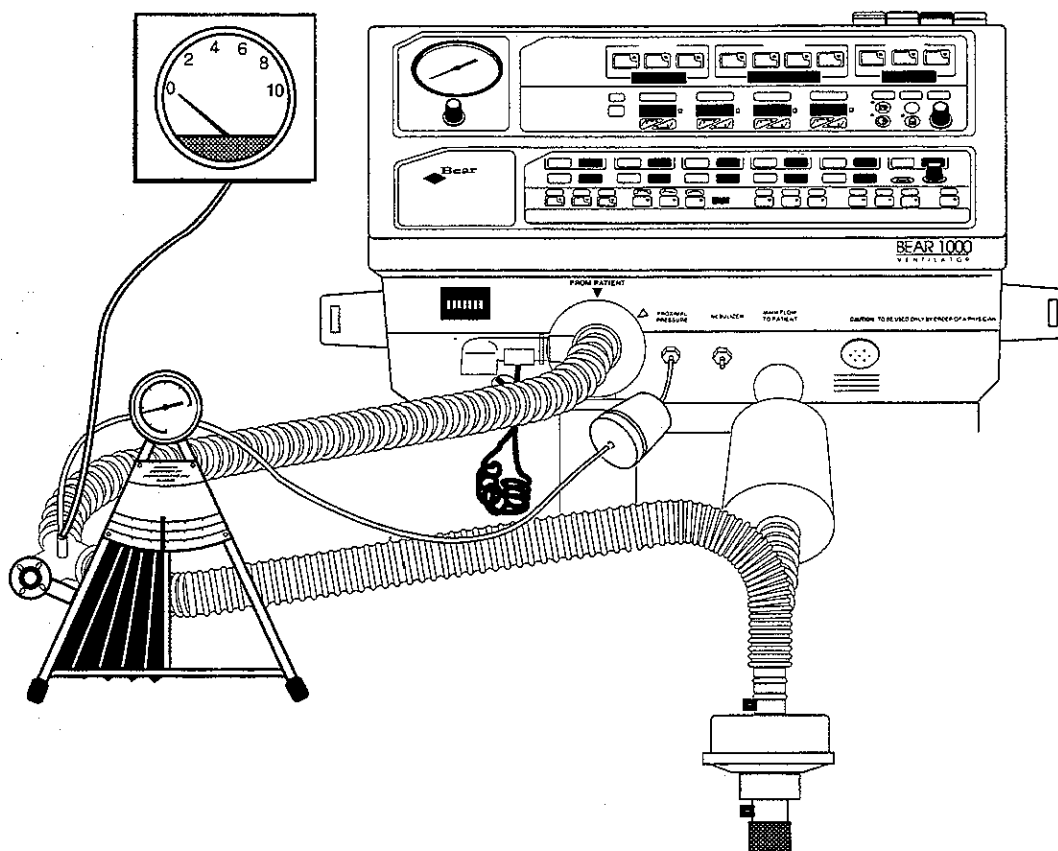


Figure 3-7

ASSIST SENSITIVITY VERIFICATION

1. Set the ventilator as shown in Table 1, except set the Rate to 0 BPM
2. Connect the ventilator as shown in Figure 3-7, with the gauge configured to measure negative pressure.
3. Compress the test lung bellows and release while observing the test gauge.
4. Verify that the unit is triggered when the test gauge is deflected to a reading of 5 cmH₂O
5. Set the Assist Sensitivity to 1 cmH₂O
6. Compress the test lung bellows and release.
7. Verify that the unit is triggered when the test gauge is deflected to a reading of 1cmH₂O.
8. Repeat the preceding test to assure that the ventilator is operating properly.

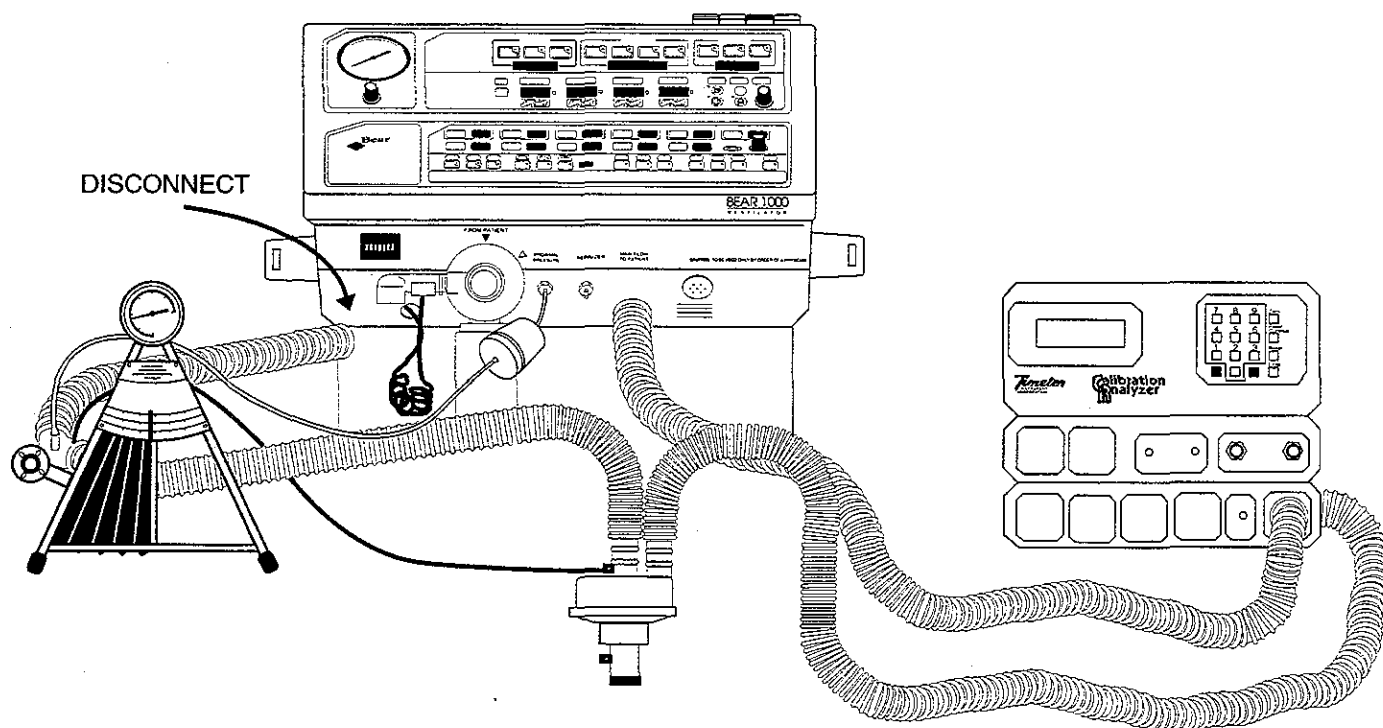


Figure 3-8

DELIVERED/EXHALED VOLUME VERIFICATION

NOTE

Volume tolerances reflect values without heating or humidification

1. Connect the ventilator and analyzer as shown in Figure 3-8.

CAUTION

Do not totally occlude the Proximal Airway tube. Doing so may result in Proximal Airway gauge damage.

2. Partially occlude the Proximal Airway tube so that approximately 10 cmH₂O is shown on the Proximal Airway gauge.
3. Set the ventilator as shown in Table 1 and vary the Tidal Volumes as shown in Table 3.
4. Verify that the Delivered Volumes are within the specified tolerances.

5. Reconnect expiratory limb and verify that exhaled volume readings at 0.10 and 0.50 liters are within a +0 % to -15% or +0.00 to -0.03 Liter (whichever is greater) tolerance range of the delivered volumes measured in step 3.

Table 3—Tidal Volume Settings

Tidal Volume Setting	Delivered Volume Tolerance
0.10	0.08 to .120 L
0.50	0.45 to 0.55
1.00	0.90 to 1.10
1.50	1.35 to 1.65
2.00	1.80 to 2.20

POWER LOSS ALARM VERIFICATION

1. Set the ventilator as shown in Table 1.
2. Disconnect AC power at the rear of the ventilator.
3. Verify that the Power Loss alarm sounds.

APPENDIX A

While the Operator Diagnostics are running, other parameters are displayed in the displays. The following is an explanation of these values. Refer to Figure 3-9.

Monitor Fields

DELIV FLOW

Shows the Delivered Flow in the range of 0 to 278 LPM.

EXT FLOW TRANSDUCER

Shows the Exhaled Flow in the range of 0 to 300 LPM.

GAS TEMP

Shows the Gas Temperature as measured at the Flow Control Valve in the range of 50 to 104 degrees F.

PROXIMAL TRANSDUCER

Shows the pressure seen by the Proximal Pressure Transducer in the range of -60 to 140 cmH₂O.

DELTA TRANSDUCER

Shows the pressure seen by the DELTA (differential) Pressure Transducer in the range of -140 to 60 cmH₂O.

MACHINE TRANSDUCER

Shows the pressure seen by the Machine Pressure Transducer in the range of 0 to 160 cmH₂O.

FCV PRESSURE TRANSDUCER

Shows the Flow Control Valve Pressure Transducer output in the range of 0 to 20 psig.

NOTE

The next displays uses each character as a separate indicator and reads from left to right. Each character displays either a 1 (active) or a 0 (inactive) state.

FCV/FAN

Character one will indicate that the Flow Control Valve is at its high end stop (maximum flow).

Character two will indicate that the Flow Control Valve is at its low end stop (zero flow).

Character three will indicate that the Cooling Fan within the ventilator is producing an operating signal.

AIR & O₂ SWITCH

Character one is not used at this time and the position will be blank.

Character two indicates that the Air Inlet Pressure Transducer is sensing sufficient inlet pressure.

Character three indicates that the Oxygen Inlet Pressure Transducer is sensing sufficient inlet pressure.

BLENDER/FLOW TRANSDUCER

Character one indicates that the Blending Control Valve is at its High Stop (100% oxygen).

Character two indicates that the Blending Control Valve is at its Low Stop (21% oxygen).

Character three indicates that the Flow Transducer is drawing an nominal amount of current (neither open/disconnected or shorted).

SOFTWARE REVISION

Shows software revision.

FCV/BLENDER COUNT

Counts from 0 to 120 as Flow Valve moves.
Counts from 0 to 124 as Blender moves.

FCV/BLENDER COUNT

Counts from 0 to 120 as Flow Valve moves.
Counts from 0 to 124 as Blender moves.

Control Fields

BAROMETRIC PRESSURE SET

Displays the current barometric pressure setting in the range of 10.5 to 14.7 psig. When this field is selected the value may be adjusted in increments of 0.1 by rotating the Set Knob.

Converting Altitude to Avg. Barometric Pressure

Feet	Meters	Barometric Pressure (psia)
0	0	14.7
500	152	14.4
1000	305	14.2
1500	457	13.9
2000	610	13.7
2500	762	13.4
3000	914	13.2
3500	1067	12.9
4000	1219	12.7
5000	1524	12.2
6000	1829	11.8
7000	2133	11.4
8000	2438	11.0
9000	2743	10.5

BAUD RATE SET

Displays the four RS-232 Baud rates

available as follows:

1.2	=	1200 Baud
2.4	=	2400 Baud
9.6	=	9600 Baud
19.2	=	19200 Baud

When this field is selected, the user may select one of the other three rates using the Set knob.

BEAR® 1000 VENTILATOR OPERATIONAL VERIFICATION CHECK LIST

This checklist is for use during the BEAR® 1000 Operational Verification

BEAR® 1000 Serial Number _____ Hour meter reading _____ Today's date _____

Configuration Code _____

Service Location _____

Address _____

City, State, Zip _____

Contact _____

Phone (____) _____

Service organization _____

Address _____

City, State, Zip _____

Service Person _____

Phone (____) _____

VERIFICATION STEPS

STEP	PASS	FAIL	STEP	PASS	FAIL
Inspection and cleaning performed	<input type="checkbox"/>	<input type="checkbox"/>	Air and O ₂ Check Valves	<input type="checkbox"/>	<input type="checkbox"/>
Display Panel Verification	<input type="checkbox"/>	<input type="checkbox"/>	Air and O ₂ Inlet Pressure Gauges	<input type="checkbox"/>	<input type="checkbox"/>
Power Up Diagnostics (d1)	<input type="checkbox"/>	<input type="checkbox"/>	Alarm Loudness Test	<input type="checkbox"/>	<input type="checkbox"/>
Flow Control Valve Test (d2)	<input type="checkbox"/>	<input type="checkbox"/>	Breath Rate Verification	<input type="checkbox"/>	<input type="checkbox"/>
Blender Control Valve Test (d3)	<input type="checkbox"/>	<input type="checkbox"/>	Oxygen Blending Verification	<input type="checkbox"/>	<input type="checkbox"/>
Leak Test (d4)	<input type="checkbox"/>	<input type="checkbox"/>	Assist Sensitivity Verification	<input type="checkbox"/>	<input type="checkbox"/>
Flow Delivery/External Flow Test (d5)	<input type="checkbox"/>	<input type="checkbox"/>	Delivered/Monitored Volume Verification	<input type="checkbox"/>	<input type="checkbox"/>
SOPR System Test (d6)	<input type="checkbox"/>	<input type="checkbox"/>	Power Loss Test	<input type="checkbox"/>	<input type="checkbox"/>
Pressure Delivery/Pressure Sensing Test (d7)	<input type="checkbox"/>	<input type="checkbox"/>			

WARNING

Do not release the ventilator for use if it does not pass all of the verification procedures specified in the checklist. To do so could result in personal injury including death or property damage. Refer the ventilator to a Bear Medical Service Technician or a Bear Medical Systems trained service technician for appropriate repair and/or calibration.

Signature _____

PROCEDURE COMPLETE

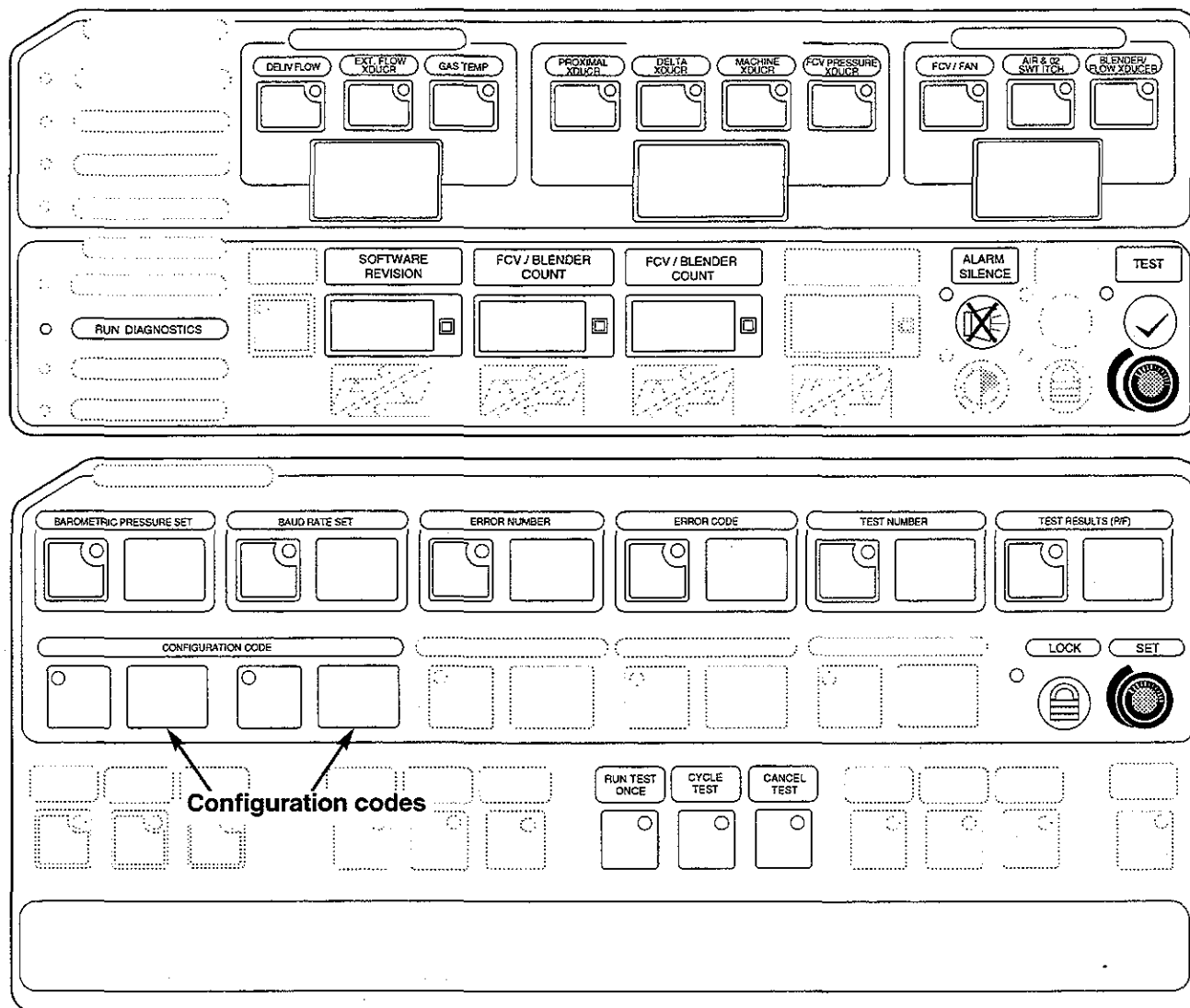


FIGURE 3-9

Active Functions and Displays for Operator Diagnostics

Section 4

BEAR® 1000 Ventilator

Updates

Section 5

BEAR® 1000 Ventilator

Calibration

Cautions and Warnings.....	1
Test Equipment	2
Proximal Pressure Transducer	2
Differential Pressure Transducer	3
Machine Pressure Transducer	4
FCV Pressure Transducer	5
Air & O2 Transducers	5
D/A Converter	7
Exhalation Valve Regulator.....	7
Inlet Check Valves.....	8
Air / O2 Balance	8
Nebulizer Calibration	8

INTRODUCTION

The information in this section is intended for use by a Bear Medical Systems factory trained service technician. Before opening the console or removing assemblies to perform calibration a reference should be made to the Instruction Manual and Sections 1, 2, 3, and 7 of this Manual to assure that the ventilator is being properly utilized.

WARNING

The calibration procedures contained in this section must be completed when any part/assembly has been removed and/or replaced. Failure to do so could result in ventilator malfunction and injury or death to the patient.

NOTE

The Operational Verification Procedure (OVP) is always performed prior to use of this section.

PROCESS

Complete the test or series of calibration verification tests necessary. Make an analysis and judgment as to what assemblies to calibrate and/or replace. If calibration is required, perform the calibration procedures following the calibration verification procedure in this document. If replacement of an assembly is required, refer to the Replacement Section (Section 8) for instructions.

WARNING

After calibration and/or replacement of any assembly(ies), always repeat the Operational Verification Procedure (Section 3), then allow a "BURN-IN" period and repeat the Operational Verification

NOTE

If problems are incurred in obtaining the calibration performance, refer to the Troubleshooting section (Section 7) or contact your dealer or Bear Medical Systems, Inc., Service Facility.

WARNING

Oxygen Vigorously accelerates combustion. DO NOT use any gauges, valves or other equipment that has been exposed to oil or grease contamination to avoid violent ignition.

WARNING

Hazardous Voltages exist within the ventilator. Always observe appropriate safety precautions when working on the ventilator while the machine is connected to an electrical power source to prevent possible accidental injurious electrical shock.

WARNING

When high pressure gas sources are connected to the ventilators, always use extreme caution when attempting to measure internal pressures. Abnormal conditions may exist where measured pressures exceed the burst pressure of the gauge, resulting in possible injury.

CAUTION

Before using any test equipment (electronic or pneumatic) for calibration procedure (other than operational verification), the accuracy of the instruments must be certified by a testing laboratory. The laboratory master test instruments must be traceable to the US Bureau of Standards or equivalent. When variances exist between the indicated and actual values, the calibration curves (proved by the testing laboratory) must be used to establish the actual correct values. This certification procedure should be performed at least once every six months. More frequent certification may be required based on usage and environment.

TEST EQUIPMENT

Part Number	Description
	BEAR® 1000 OVP
	BEAR® 1000 Maintenance Manual
50000-01000	Hose Assy, DISS Air, 12 ft.
50000-01001	Hose Assy, DISS O ₂ , 12 ft.
50000-01120	Assy, Exhalation Valve Water Collector
51000-20101	Manley Test Lung or equivalent
52000-01036	O ₂ Relay Adjustment Tool
	Pressure Gauge 0-200 cmH ₂ O, ± 1% F.S. accuracy or digital equivalent
	Pressure Gauge 0-50 psi, ± 1% F.S. accuracy or digital equivalent
	Digital Voltmeter
	Patient Circuit (adult)
	Adjustable Pressure Regulator (0-50 PSI).
	Adjustable Pressure Regulator (0-2 PSI).
	Mini Strap Wrench

NOTE

All specification values are nominal. Variance in test equipment must be taken into consideration. Test equipment must be periodically checked to verify conformance to the manufacturer's specifications.

PRELIMINARY

Accessing Inside The Unit

Remove the single screw to the right of the Oxygen Inlet. Tilt the top of the unit up until it remains in an upright position.

Diagnostic Calibration Set Up:

Press and hold the diagnostic push switch while turning on the units power switch. The diagnostic push switch is located on the left side of Monitor board as viewed from the rear (See Figure 5-1).

Refer to Figure 5-3 for the redefined functions of the Control and Monitor Panels to perform the calibrations.

TRANSDUCER CALIBRATION

NOTE

Do not connect external gas sources to the ventilator until instructed to do so.

Proximal Pressure Transducer Calibration:

1. Remove the tubing from the Proximal Pressure Transducer.

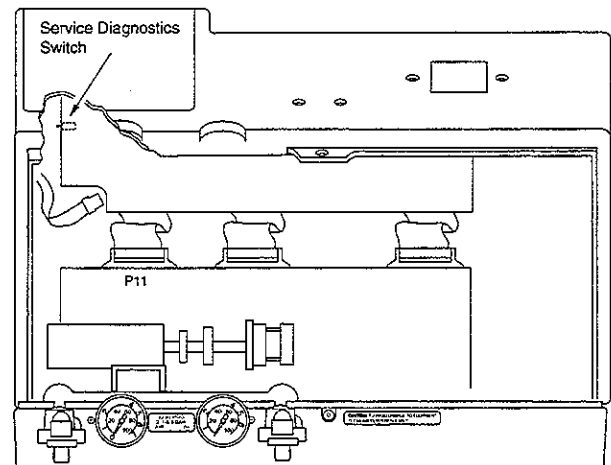


Figure 5-1
Service Diagnostics Switch Location

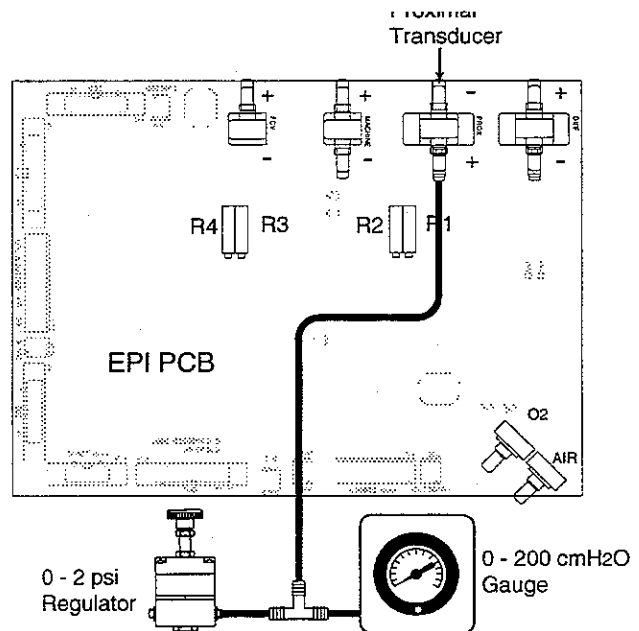


Figure 5-2
Proximal Transducer Calibration

2. Select Channel Number 1.
3. Select Calibration Point 0.
4. Adjust R2, if required, to obtain a reading of 307 ±10 in the Current Count window.
5. Select and set 00.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows.
6. Press the Set Point key to program the new calibration point.
7. Connect the Proximal Transducer as shown in Figure 5-2 and apply 95 ±.5 cmH₂O pressure.

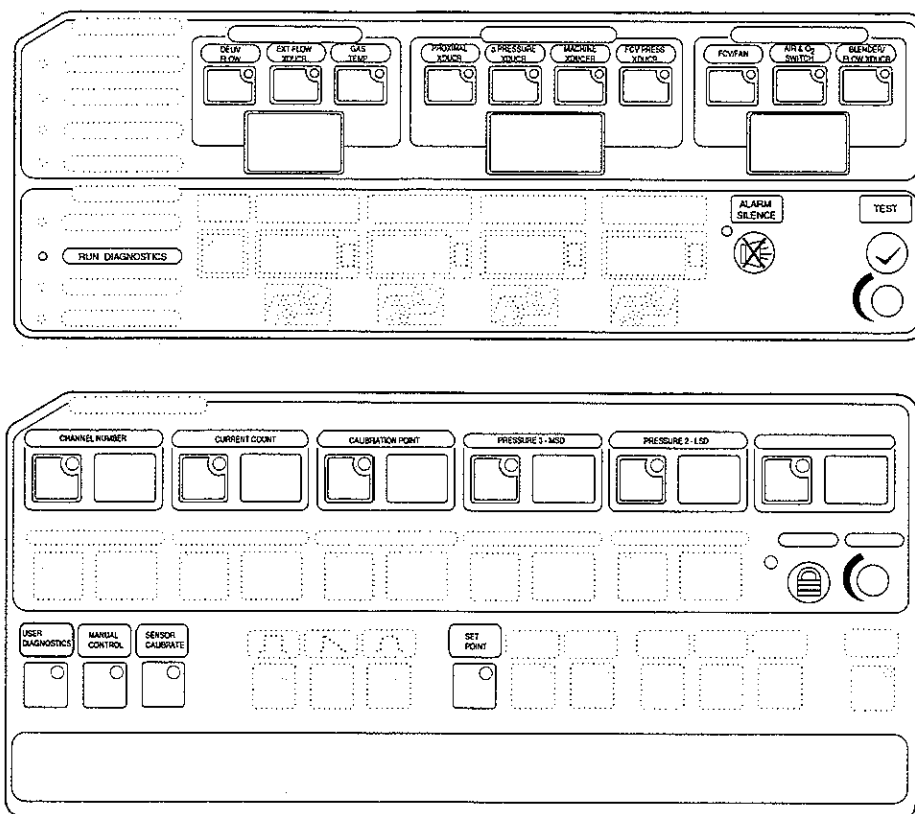


Figure 5-3
Active Controls for Calibration Mode

8. Select Calibration Point P.
9. Select and set 95.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows.
10. Press the Set Point to program the new calibration point.
11. Connect the Proximal Transducer as shown in Figure 5-2 except to the opposite port (negative) and apply 40 ±.5 cmH₂O pressure.
12. Select Calibration Point n.
13. Select and set 40.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows.
14. Press the Set Point to program the new calibration point.
15. Connect the tubing back to the Proximal Pressure Transducer.

Differential Pressure Transducer Calibration:

1. Remove the tubing from the Differential Pressure Transducer.
2. Select Channel Number 2.
3. Select Calibration Point 0.

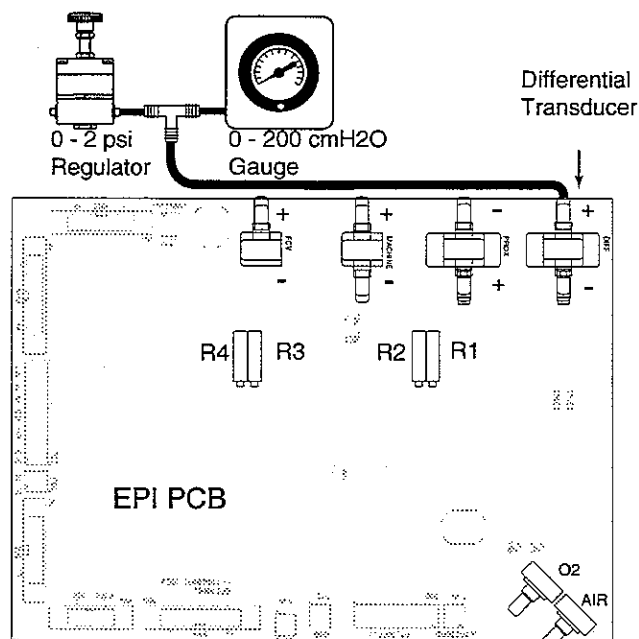


Figure 5-4
Differential Transducer Calibration

4. Select and set 00.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows
5. Adjust R1, if required, to obtain a reading of 716 ± 10 in the Current Count window.
6. Press the Set Point key to program the new calibration point.
7. Connect the Differential Transducer as shown in Figure 5-4 and apply 40 ± 5 cmH₂O pressure.
8. Select Calibration Point P.
9. Select and set 40.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows.
10. Press the Set Point to program the new calibration point.
11. Connect the Differential Transducer as shown in Figure 5-4 except to the opposite port (negative) and apply 95 ± 5 cmH₂O pressure.
12. Select Calibration Point n.

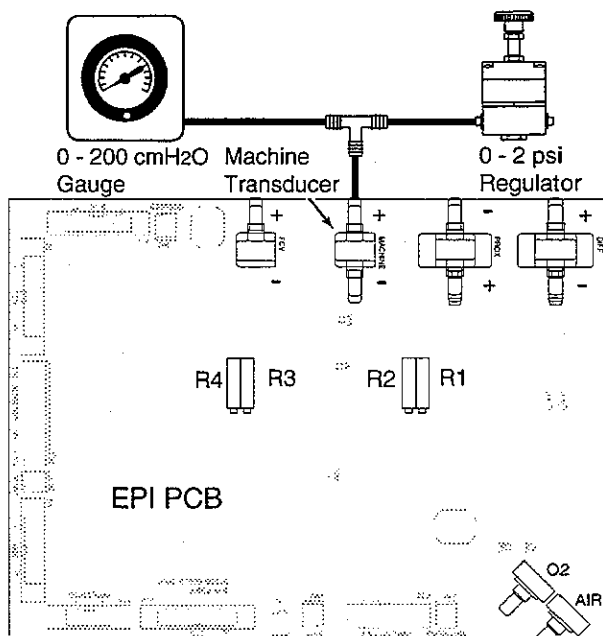


Figure 5-5
Machine Transducer Calibration

13. Select and set 95.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows.
14. Press the Set Point to program the new calibration point.
15. Connect the tubing back to the Differential Pressure Transducer.

Machine Pressure Transducer Calibration:

1. Remove the tubing from the Machine Pressure Transducer.
2. Select Channel Number 3.
3. Select Calibration Point 0.
4. Adjust R3, if required, to obtain a reading of 204 ± 10 in the Current Count window.
5. Select and set 00.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows.
6. Press the Set Point key to program the new calibration point.

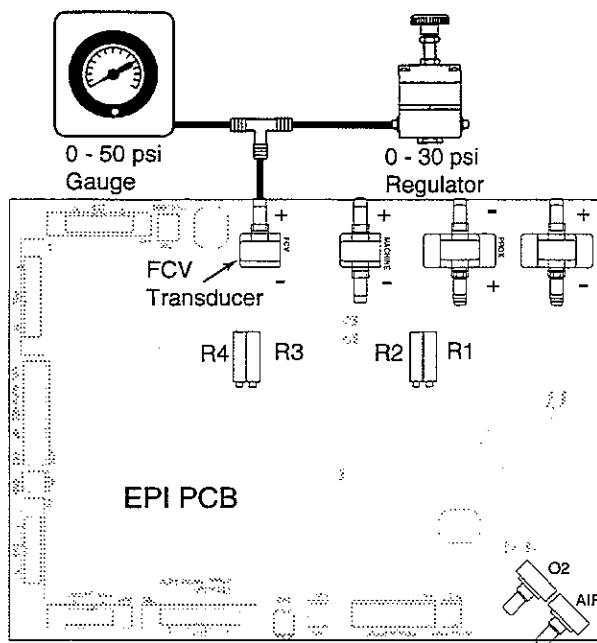


Figure 5-6
FCV Transducer Calibration

7. Connect the Machine Transducer as shown in Figure 5-5 and apply 120 ± 5 cmH₂O pressure.
8. Select Calibration Point P.
9. Select and set 120.00 cmH₂O in the Pressure 3 MSD and Pressure 2 LSD windows.
10. Press the Set Point to program the new calibration point.

11. Connect the tubing back to the Machine Pressure Transducer.

FCV Pressure Transducer Calibration:

1. Remove the tubing from the FCV Pressure Transducer.
2. Select Channel Number 4.
3. Select Calibration Point 0.
4. Adjust R4, if required, to obtain a reading of 100 ± 10 in the Current Count window.

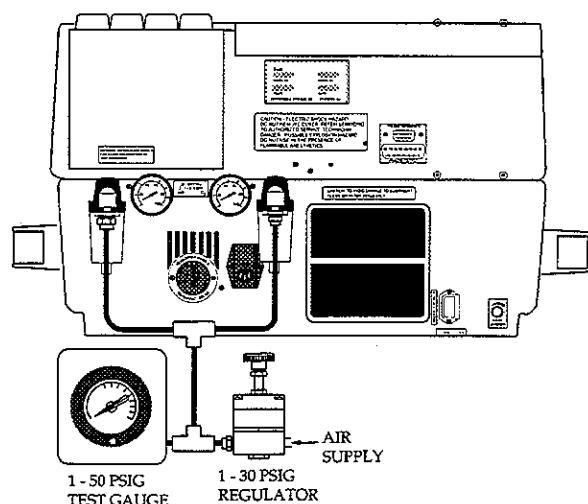


Figure 5-7
Air & O2 Transducer Calibration

5. Select and set 00.00 cmH2O in the Pressure 3 MSD and Pressure 2 LSD windows.
6. Press the Set Point key to program the new calibration point.
7. Connect the FCV Transducer as shown in Figure 5-6 and apply $12 \pm .5$ psig pressure.
8. Select Calibration Point P.
9. Select and set 12.00 psig in the Pressure 3 MSD and Pressure 2 LSD windows.
10. Press the Set Point to program the new calibration point.
11. Connect the tubing back to the FCV Pressure Transducer.

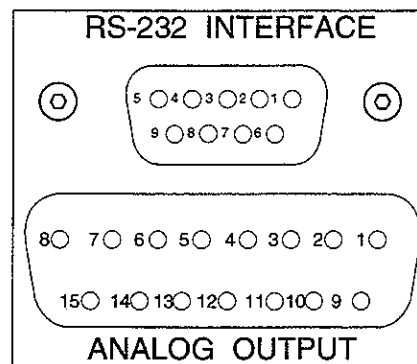


Figure 5-8
Interface Pin Locations

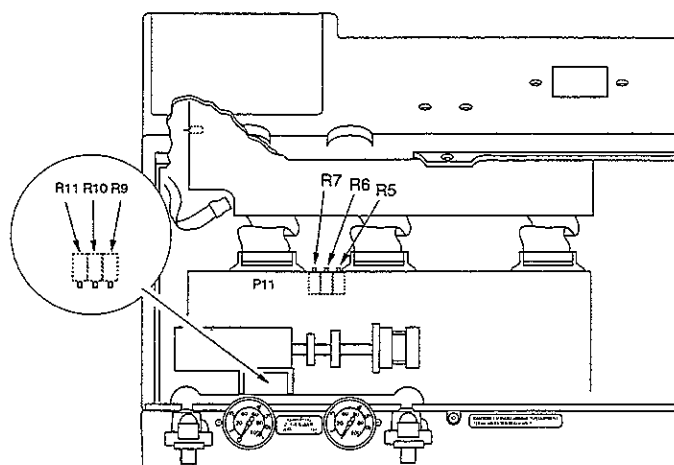


Figure 5-9
D/A Calibration Potentiometers

Air & O2 Pressure Transducers Calibration:

1. Connect an external gas source and gauge to the ventilator as shown in Figure 5-7.
2. Select Channel Number 5 (Air).
3. Select Calibration Point P.
4. Adjust the external gas source for $28.50 \pm .50$ psi.
5. Select and set 28.50 psi in the Pressure 3 MSD and Pressure 2 LSD windows.
6. Press the Set Point to program the new calibration point.
7. Select Channel Number 6 (O2).

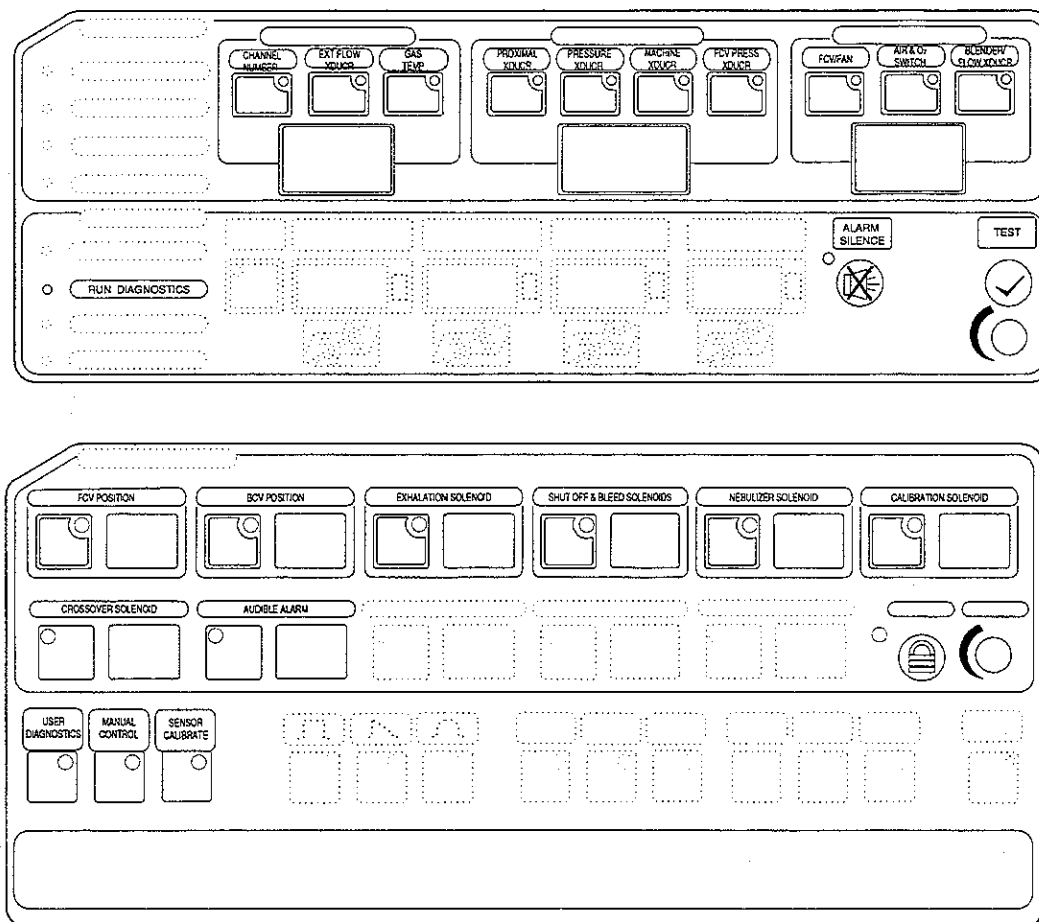


Figure 5-10
Active Controls in Manual Mode

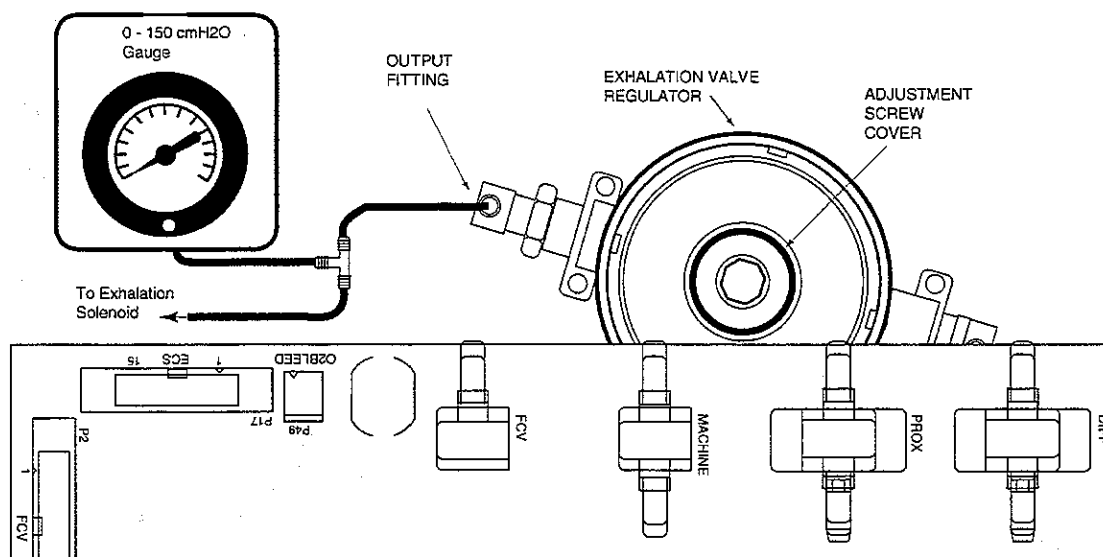


Figure 5-11
Exhalation Valve Regulator Calibration

8. Select Calibration Point P.
9. Press the Set Point to program the new calibration point.

D/A Converter Calibration

NOTE

There have been two designs of the Control PCB. These are interchangeable but the location of the potentiometers and their designations. Refer to Figure 5-9.

1. Select Channel Number 7.
2. Press the Set Point key.
3. Referring to Figure 5-8, measure the voltage between Pin 2 (ground) and Pin 1 of the Analog Output connector (Pressure Channel 0).
4. If this does not measure 5.000 ± 0.005 Vdc, adjust R5 or R9 on the Control PCB (The pots are on the component side of the PCB in the positions indicated in Figure 9).
5. Measure the voltage between Pin 4 (ground) and Pin 3 (Flow Channel 1).
6. If this does not measure 5.000 ± 0.005 Vdc, adjust R6 or R10 on the Control PCB.
7. Measure the voltage between Pin 6 (ground) and Pin 5 (Volume Channel 2).
8. If this does not measure 7.500 ± 0.005 Vdc, adjust R7 or R11 on the Control PCB.

Exhalation/SOPR Pressure & Over-Pressure Relief

1. Press the Manual Control key to enter the Service Diagnostics Manual mode (See Figure 5-3).
2. Tee in the pressure gauge to the Exhalation Valve Regulator output fitting as shown in Figure 5-11.
3. Press the Exhalation Solenoid key to turn on (display = 1) the Exhalation solenoid See Figure 5-10).
4. Press the Shut Off key to turn on (display = 1) the Shut Off solenoid.
5. Verify that the pressure gauge reads 140 ± 10 cmH₂O. Readjust the low pressure regulator if necessary.
6. If required, remove the Adjustment Screw Cover and adjust the Exhalation Valve regulator to achieve 140 ± 10 cmH₂O

7. Remove the pressure gauge and turn off (display = 0) both solenoids.
8. Press the FCV POSITION key and turn the SET knob until the Flow Control valve opens to maximum position.
9. Disconnect the Proximal Airway line at the BEAR® 1000 and connect it to the pressure gauge.

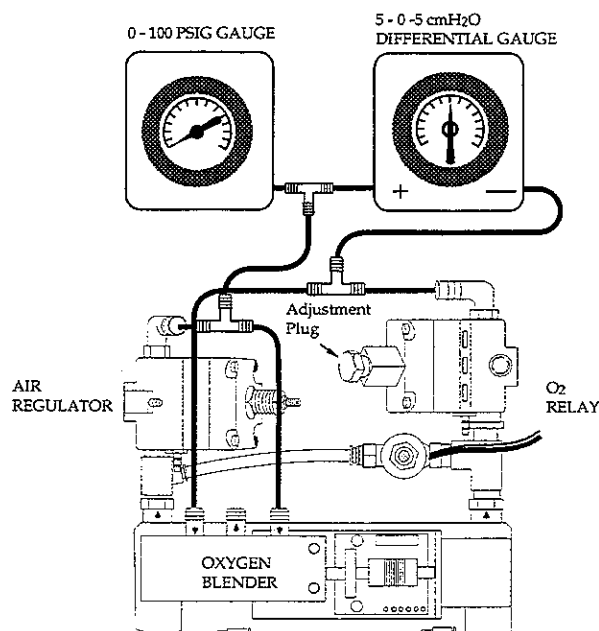
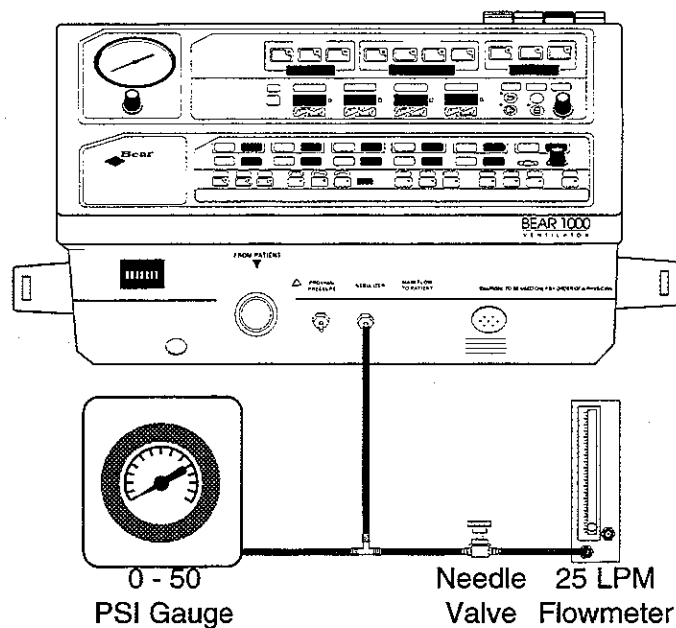


Figure 5-12
Air & O₂ Regulator Calibration

10. Press the Exhalation Solenoid key to turn on (display = 1) the Exhalation Solenoid.
11. Press the Shut Off Solenoid key to turn on (display = 1) the Shut Off Solenoid.
12. Verify that the SOPR valve is popped open to relieve the pressure and the maximum pressure in the patient circuit is between 121 to 175 cmH₂O as shown on the pressure gauge.
13. Turn off the Shut-Off solenoid, Exhalation solenoid and close the Flow Control valve.
14. Connect a patient circuit to the Manley test lung from the ventilator and set the Manley to C50 and zero resistance.
15. Verify that the gas can flow from the dump port to the patient outlet port by pulling the Manley's bellows.



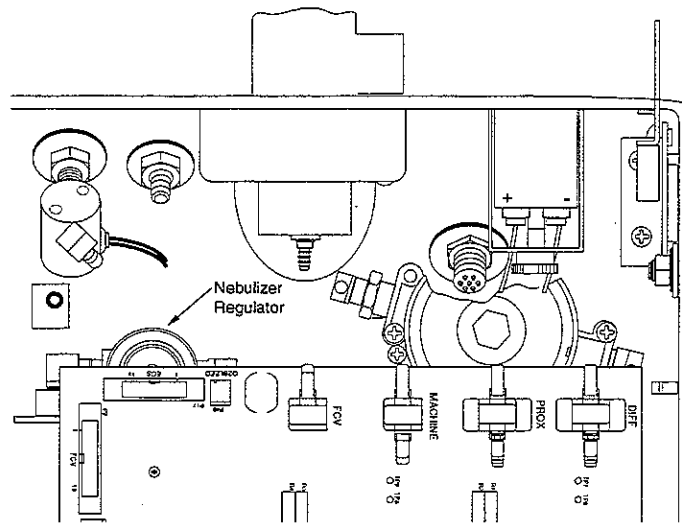
**Figure 5-13
Nebulizer Calibration**

Inlet Check Valves Test

1. Set the Crossover Solenoid to 1 (open).
2. Set the BCV Position to mid range (approximately 60).
3. Apply approximately 50 psi to the air inlet port and verify that there is zero flow (bubble tight) coming out at the O2 inlet port.
4. Apply approximately 50 psi to the O2 inlet port and verify that there is zero flow (bubble tight) coming out at the Air inlet port.
5. Set the Crossover Solenoid to 0 (closed).

Air/O2 Pressure Balance

1. Set the Shut Off & Bleed Solenoids to 1 (open).
2. Connect the ventilator as shown in figure 5-12 and apply 50 psi air and O2.
3. Verify that the air regulator output pressure is 18.0 ± 0.1 PSIG. Readjust the Air regulator if necessary.



**Figure 5-14
Nebulizer Regulator**

4. Air/O2 differential shall be 0 ± 2 cmH2O.
5. If required, remove the plug from the O2 relay and adjust using the O2 Relay adjustment tool.
6. Set the Shut Off & Bleed Solenoids to 0 (closed).

Nebulizer Calibration

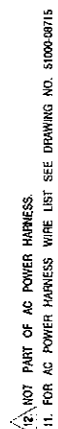
1. Connect the test equipment to the ventilator as shown in Figure 5-13.
2. Fully close the needle valve.
3. Turn on the ventilator in Service Diagnostics mode and enter the Manual Control mode.
4. Activate the Nebulizer Solenoid (Ref. Figure 5-10).
5. The gauge should read 10 ± 0.5 psi.
6. If required, adjust the Nebulizer Regulator by pulling up the locking ring and turning the center knob (Ref Figure 5-14).
7. Open the needle valve to obtain a flow of 6 ± 2.0 LPM on the flowmeter.
8. Open the Flow Valve for a position indication of 40.
9. Observe that the gauge reads a minimum of 8.5 psi.

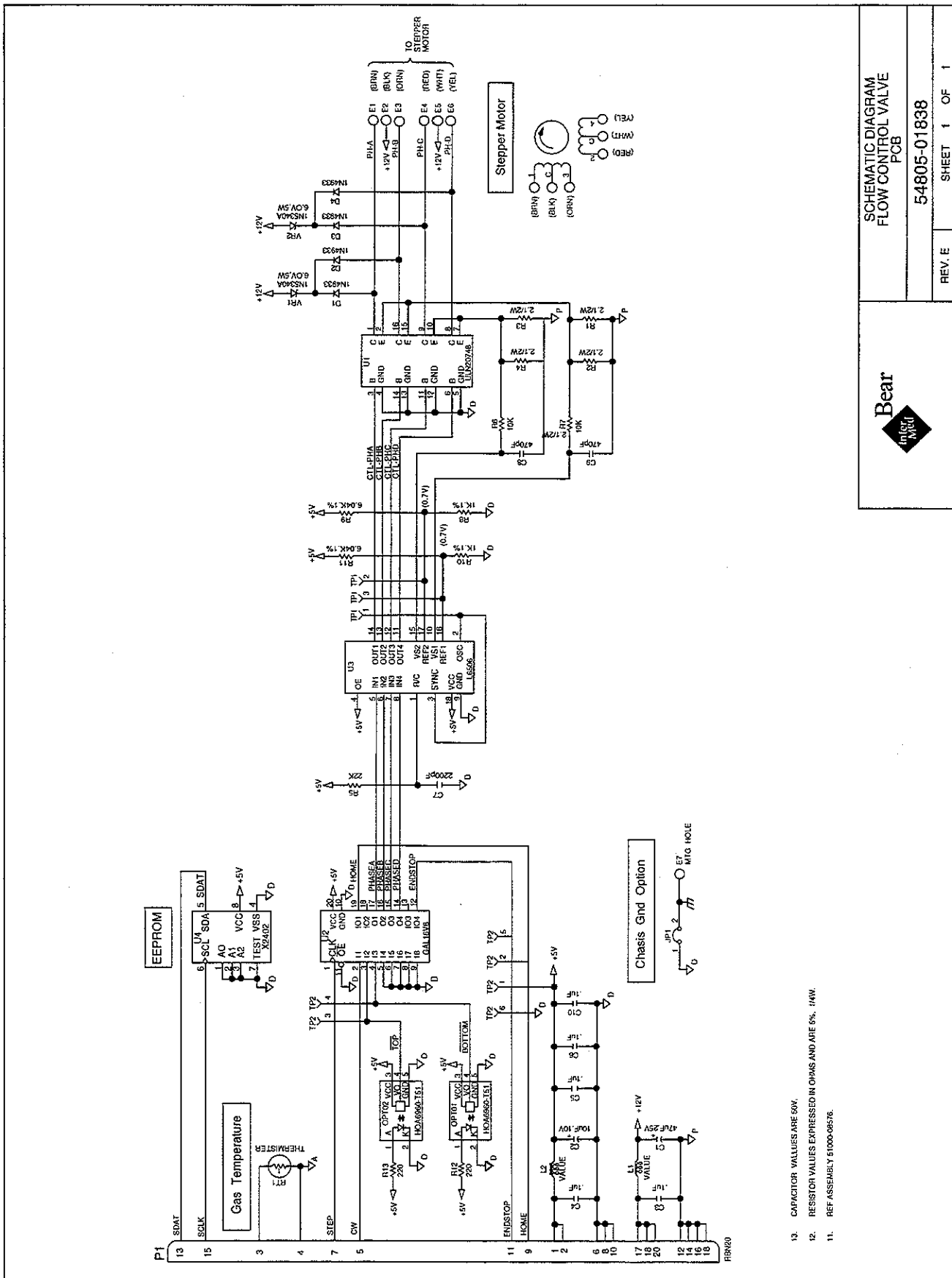
Section 6

BEAR® 1000 Ventilator

Schematics

System Wiring Diagram	1
Flow Control Board PCB	2
Power Supply Module	3
Control PCB	4
Monitor PCB	8
Pneumatic Tubing Installation.....	10
Electro-Pneumatic interface.....	12
External Flow Sensor.....	16
Oxygen Blender	17





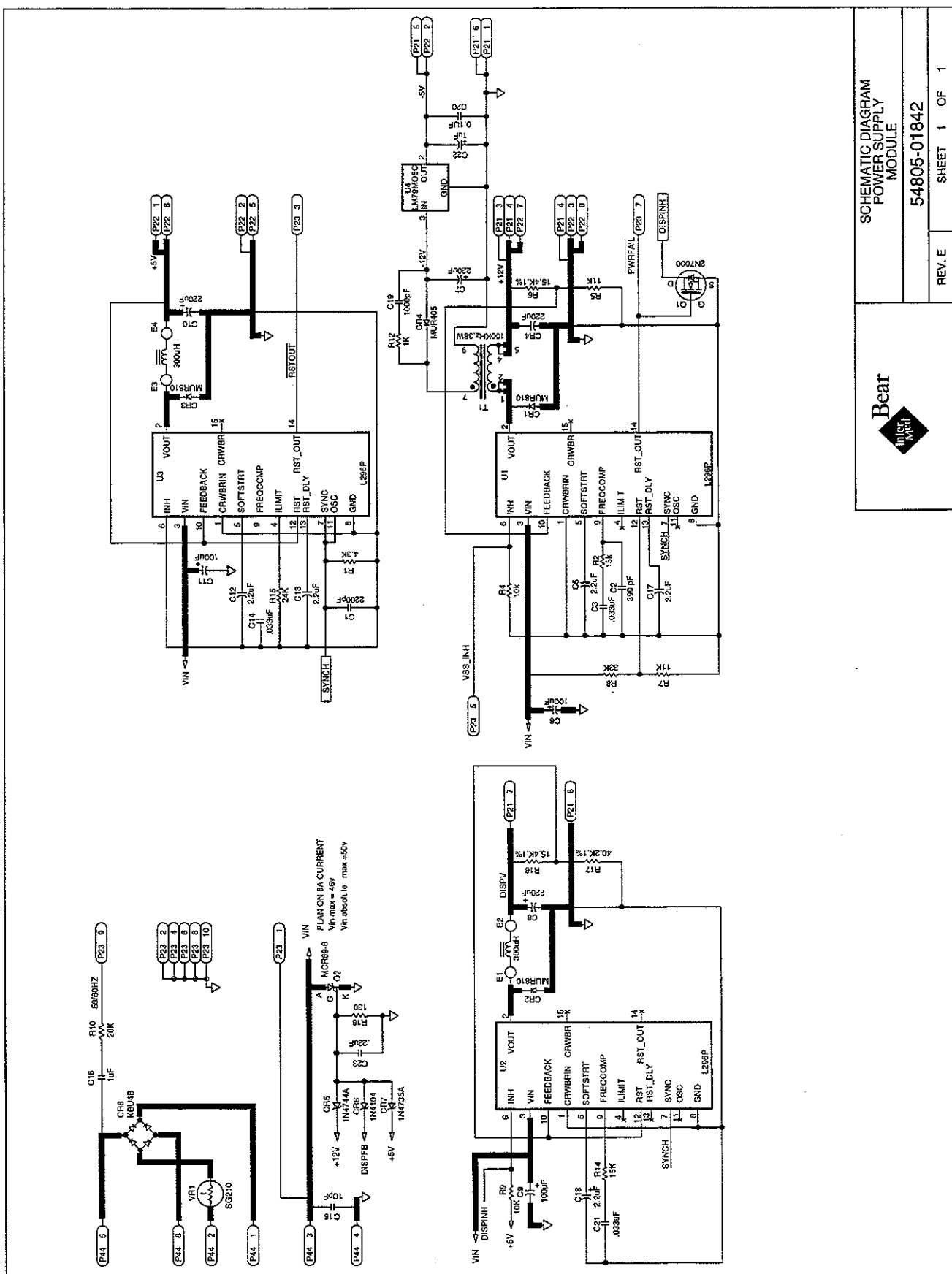
13. CAPACITOR VALUES ARE 50V.
12. RESISTOR VALUES EXPRESSED IN OHMS AND ARE 5%, 14W.
11. REF ASSEMBLY 51000-08576.

SCHEMATIC DIAGRAM
FLOW CONTROL VALVE
PCB



54805-01838

REV. E SHEET 1 OF 1



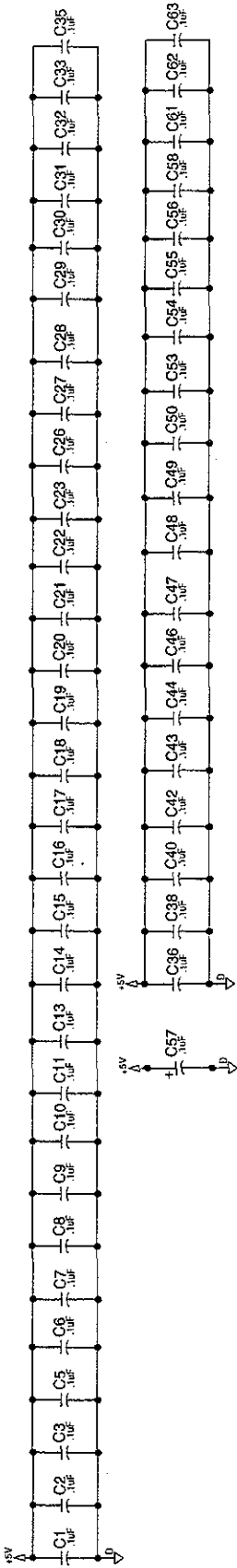
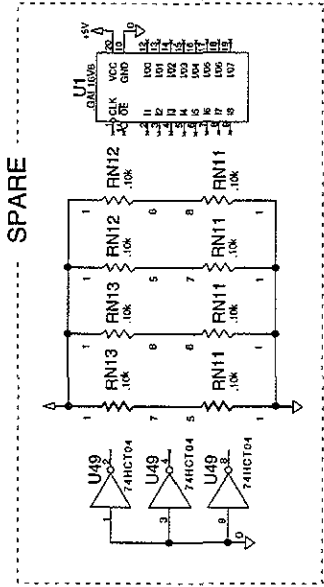
SCHEMATIC DIAGRAM
POWER SUPPLY
MODULE

54805-01842

REV. E SHEET 1 OF 1

U#	DESC.	VCC	GND
1	SPARE	20	10
8	74HCT245	20	10
20	SN75116	16	8
25	5895A2	15	1
23	74HCT259A	16	8
39	5895A2	15	1
40	5895A2	15	1
41	5895A2	15	1
42	5895A2	15	1
43	5895A2	15	1
44	5895A2	15	1
45	5895A2	15	1
46	5895A2	15	1
47	74HCT04	14	7
48	74HCT04	14	7
49	74HCT04	14	7
65	SCC2692	40	20
66	74HCT32	14	7
67	74HCT174	14	7
69	74HCT174	14	7
70	8237A-5	31	20
72	GAL16V8	20	10
73	80188	9.43	26.60
74	74HCT373	20	10
77	74HCT374	20	10

U#	DESC.	VCC	GND
82	74HCT374	20	10
83	74HCT373	20	10
84	74HCT138	16	8
85	6284	14	14
86	270512	28	14
87	74HCT374	20	10
88	74HCT374	20	10



- △ SOCKET (U86) INSTALLED ON ASSY, EPROM (U86) NOT INSTALLED ON ASSY.
4. NC INDICATES NO CONNECT.
3. CAPACITOR VALUES ARE 50V.
2. RESISTOR VALUES EXPRESSED IN OHMS AND ARE 5% 1/4W.
1. REF ASSEMBLY 51000-08874.



SCHEMATIC DIAGRAM,
CONTROL PCB

54805-01839

REV. G SHEET 1 OF 4

